OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
10-F-0002

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

WALTER REED ARMY INSTITUTE OF RESEARCH
DIV. OF VETERINARY MEDICINE, BLDG 511
503 ROBERT GRANT AVE
SILVER SPRING, MD 20910

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	4	0	0	4
6. Guinea Pigs	17	60	26	498	584
7. Hamsters	0	113	3	0	116
8. Rabbits	0	0	0	0	0
9. Non-human Primates	495	45	59	0	104
10. Sheep	0	0	34	0	34
11. Pigs	0	0	234	0	234
12. Other Farm Animals					
13. Other Animals	166	39	0	0	39

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		28-JAN-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
10-F-0002

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

WALTER REED ARMY INSTITUTE OF RESEARCH
DIV. OF VETERINARY MEDICINE, BLDG 511
503 ROBERT GRANT AVE
SILVER SPRING, MD 20910

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	3	0	0	3
SAND RATS	166	36	0	0	36

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
28-JAN-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCES
UNIV. OF THE HEALTH SCIENCES
4301 JONES BRIDGE RD.
BETHESDA, MD 20814

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	36	0	36
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	181	0	181
12. Other Farm Animals	0	0	10	0	10
13. Other Animals	0	169	21	0	190

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		20-NOV-2013

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCES
UNIV. OF THE HEALTH SCIENCES
4301 JONES BRIDGE RD.
BETHESDA, MD 20814

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	8	21	0	29
GERBILS	0	161	0	0	161

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
20-NOV-2013

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0021

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY MED RESEARCH INST OF INFECTIOUS DISEASE
VETERINARY MEDICINE DIVISION
1425 PORTER ST
FREDERICK, MD 21702

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	304	53	843	682	1578
7. Hamsters	0	36	538	356	930
8. Rabbits	0	6	56	0	62
9. Non-human Primates	43	438	391	260	1089
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	32	6	0	38
13. Other Animals	0	2	0	0	2

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0003

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

ARMED FORCES RADIOBIOLOGY RESEARCH INST.
AFRRI/VSD
8901 WISCONSIN AVENUE, BLDG 43
BETHESDA, MD 20889

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	16	25	10	58	93
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	4	4
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		31-JAN-2014

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0005

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY PUBLIC HEALTH COMMAND
5158 BLACKHAWK RD

ABERDEEN PROV GRND, MD 21010

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	33	1	34
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	1	111	0	112

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		27-JAN-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0005

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY PUBLIC HEALTH COMMAND
5158 BLACKHAWK RD

ABERDEEN PROV GRND, MD 21010

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
DEER MICE	0	0	104	0	104
WHITE FOOTED MICE	0	0	3	0	3
WESTERN HARVEST MICE	0	0	2	0	2
HOUSE MICE	0	0	2	0	2
HISPID COTTON RATS	0	1	0	0	1

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
27-JAN-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0006

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY MED RESEARCH INST OF CHEMICAL DEFENSE
COMMANDER
3100 RICKETTS POINT ROAD
ABERDEEN PROV GRND, MD 21010

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	14	955	196	3487	4638
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	78	0	78
9. Non-human Primates	70	68	19	22	109
10. Sheep	0	0	0	0	0
11. Pigs	0	17	11	49	77
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0008

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

NATIONAL CANCER INSTITUTE AT FREDERICK
BUILDING 1021
P O BOX B
FREDERICK, MD 21702

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	2	0	0	2
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		29-NOV-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0016

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

NATIONAL INSTITUTE OF HEALTH
31 CENTER DRIVE, ROOM B1C37
OFFICE OF ANIMAL CARE AND USE
BETHESDA, MD 20892

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	367	154	0	521
5. Cats	0	0	0	0	0
6. Guinea Pigs	110	597	0	76	673
7. Hamsters	1268	954	5	578	1537
8. Rabbits	0	248	116	0	364
9. Non-human Primates	589	2416	941	73	3430
10. Sheep	0	2	0	0	2
11. Pigs	2	16	188	10	214
12. Other Farm Animals					
13. Other Animals	1221	932	11	91	1034

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		27-JAN-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0016

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

NATIONAL INSTITUTE OF HEALTH
31 CENTER DRIVE, ROOM B1C37
OFFICE OF ANIMAL CARE AND USE
BETHESDA, MD 20892

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
GERBILS	0	2	0	0	2
WILD MICE	1058	203	0	14	217
FERRETS	0	284	11	75	370
AFRICAN THICKET RATS	163	167	0	2	169
GROUND SQUIRRELS	0	276	0	0	276

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c) [redacted]

DATE SIGNED
27-JAN-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0019

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY EDGEWOOD CHEMICAL BIOLOGICAL CTR
BLDG E3150 ATTN: AMSRD-ECB-RT-TV

ABERDEEN PROV GRND, MD 21010

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	6	20	299	325
7. Hamsters	0	0	0	0	0
8. Rabbits	0	99	106	236	441
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	8	32	40
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		28-JAN-2014

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0021

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY MED RESEARCH INST OF INFECTIOUS DISEASE
VETERINARY MEDICINE DIVISION
1425 PORTER ST
FREDERICK, MD 21702

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	304	53	843	682	1578
7. Hamsters	0	36	538	356	930
8. Rabbits	0	6	56	0	62
9. Non-human Primates	43	438	391	260	1089
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	32	6	0	38
13. Other Animals	0	2	0	0	2

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0024

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

CENTER FOR BIOLOGICS EVALUATION & RESEARCH
FOOD AND DRUG ADMINISTRATION
10903 NEW HAMPSHIRE AVE WHITE OAK BUILDING 71, ROOM 6266
SILVER SPRING, MD 20993

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	37	462	56	555
7. Hamsters	0	168	205	0	373
8. Rabbits	0	107	7	0	114
9. Non-human Primates	0	110	27	0	137
10. Sheep	0	24	0	0	24
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	14	75	0	89

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		27-FEB-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0024

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

CENTER FOR BIOLOGICS EVALUATION & RESEARCH
FOOD AND DRUG ADMINISTRATION
10903 NEW HAMPSHIRE AVE WHITE OAK BUILDING 71, ROOM 6266
SILVER SPRING, MD 20993

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	14	75	0	89

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
27-FEB-2014

APHIS FORM 7023A
AUG 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0025

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

WHITE OAK ANIMAL PROGRAM
10903 NEW HAMPSHIRE AVE
BLDG 32 ROOM 4122
SILVER SPRING, MD 20993

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	27	0	27
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	26	0	26
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		20-NOV-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0026

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

CENTER FOR VETERINARY MEDICINE
7500 STANDISH PLACE

ROCKVILLE, MD 20855

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	4	1	30	0	31
12. Other Farm Animals	27	4	0	0	4
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		20-NOV-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0030

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

NIAID-MORGAN ISLAND
33 NORTH DRIVE MSC 3207
BLDG 33, RM 2N09H
BETHESDA, MD 20892

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	3466	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0031

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

BATTELLE NATIONAL BIODEFENSE INSTITUTE LLC
8300 RESEARCH PLAZA

FORT DETRICK, MD 21702

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	199	25	17	241
7. Hamsters	0	5	0	0	5
8. Rabbits	2	2	20	0	22
9. Non-human Primates	0	2	0	0	2
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		31-JAN-2014

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0006

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

THE JOHNS HOPKINS UNIVERSITY
265 GARLAND HALL
3400 N CHARLES STREET
BALTIMORE, MD 21218

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	83	0	83
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	426	842	0	1268
7. Hamsters	0	7	0	0	7
8. Rabbits	6	89	978	0	1067
9. Non-human Primates	414	0	332	0	332
10. Sheep	0	9	4	0	13
11. Pigs	0	8	756	0	764
12. Other Farm Animals	0	2	6	0	8
13. Other Animals	0	0	95	0	95

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		27-JAN-2014

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0006

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

THE JOHNS HOPKINS UNIVERSITY
265 GARLAND HALL
3400 N CHARLES STREET
BALTIMORE, MD 21218

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	0	50	0	50
CHINCHILLAS	0	0	45	0	45

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c) [redacted]

DATE SIGNED
27-JAN-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0008

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

INSECT CONTROL & RESEARCH INC.
1330 DILLON HEIGHTS AVENUE

BALTIMORE, MD 21228

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	10	0	0	10
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		12-DEC-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0009

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

MEDIMMUNE LLC
ONE MEDIMMUNE WAY

GAITHERSBURG, MD 20878

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	24	1616	0	1640

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0011

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SINAI HOSPITAL OF BALTIMORE INC
DEPARTMENT OF RESEARCH
2401 W BELVEDER AVE SCHAPIRO BLDG, SUITE 203
BALTIMORE, MD 21215

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	6	0	6
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	2	0	8	0	8
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-FEB-2014

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0018

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF MARYLAND BALTIMORE
10 S. PINE ST. RM G-100, MSTF BLDG.

BALTIMORE, MD 21201

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	319	1037	1356
7. Hamsters	0	0	224	0	224
8. Rabbits	0	0	54	0	54
9. Non-human Primates	0	0	426	79	505
10. Sheep	0	0	35	0	35
11. Pigs	0	0	72	0	72
12. Other Farm Animals					
13. Other Animals	0	0	29	0	29

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		30-JAN-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0018

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF MARYLAND BALTIMORE
10 S. PINE ST. RM G-100, MSTF BLDG.

BALTIMORE, MD 21201

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	0	29	0	29

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
30-JAN-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0020

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SCHOOL OF HEALTH PROFESSIONS
7201 ROSSVILLE BLVD
ALLD MASH BLDG ROOM 200
BALTIMORE, MD 21237

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	12	54	0	66
5. Cats	0	22	76	0	98
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0031

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

WASHINGTON BIOTECHNOLOGY INC
PO BOX 211

SIMPSONVILLE, MD 21150

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	15	33	18	36	87
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		30-JAN-2014

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

BIOQUAL INC
4 RESEARCH COURT

ROCKVILLE, MD 20850

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	73	967	865	0	1832
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	85	374	0	459

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-FEB-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

BIOQUAL INC
4 RESEARCH COURT

ROCKVILLE, MD 20850

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	85	374	0	459

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
03-FEB-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0038

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

LONZA GROUP LTD
8830 BIGGS FORD RD

WALKERSVILLE, MD 21793

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	28	0	28
7. Hamsters	0	0	14	0	14
8. Rabbits	0	14	4	0	18
9. Non-human Primates	0	0	0	0	0
10. Sheep	6	12	0	0	12
11. Pigs	0	0	0	0	0
12. Other Farm Animals	37	10	0	0	10
13. Other Animals	2	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-FEB-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0038

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

LONZA GROUP LTD
8830 BIGGS FORD RD

WALKERSVILLE, MD 21793

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
BURRO	2	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
03-FEB-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0046

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

THOMAS D MORRIS INC
4001 MILLENDER MILL ROAD

REISTERSTOWN, MD 21136

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	30	0	30
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	81	66	0	147
11. Pigs	0	82	136	0	218
12. Other Farm Animals	0	1	43	0	44
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		01-MAY-2014

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0050

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

BIOMEDICAL RESEARCH INSTITUTE
9410 KEY WEST AVENUE

ROCKVILLE, MD 20850

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	278	0	278
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		12-DEC-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0051

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SPRING VALLEY LABORATORIES INC
P.O. BOX 242

WOODBINE, MD 21797

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	647	2	649
7. Hamsters	0	0	12	0	12
8. Rabbits	22	0	521	0	521
9. Non-human Primates	0	0	0	0	0
10. Sheep	4	0	3	0	3
11. Pigs	4	0	27	0	27
12. Other Farm Animals	0	0	1	0	1
13. Other Animals	0	0	1	0	1

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		28-JAN-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0051

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SPRING VALLEY LABORATORIES INC
P.O. BOX 242

WOODBINE, MD 21797

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
DONKEYS	0	0	1	0	1

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
28-JAN-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0059

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

ADVANCED BIOSCIENCE LABS INC
9800 MEDICAL CENTER DRIVE
BUILDING D
ROCKVILLE, MD 20850

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	19	0	0	19
7. Hamsters	0	0	0	0	0
8. Rabbits	0	46	0	0	46
9. Non-human Primates	160	844	402	0	1246
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		21-NOV-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0072

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

MID-ATLANTIC STATES VETERINARY CLINIC
P O BOX 5407

ANNAPOLIS, MD 21403

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	11	8	0	19
13. Other Animals	16	132	14	0	146

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0082

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

BIO RELIANCE CORPORATION
14920 BROSCHART ROAD

ROCKVILLE, MD 20850

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	150	2254	0	2404
7. Hamsters	0	3	496	129	628
8. Rabbits	0	210	0	0	210
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		30-JAN-2014

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0083

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

AMERICAN RED CROSS
15601 CRABBS BRANCH WAY

ROCKVILLE, MD 20855

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	575	0	0	575
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		21-NOV-2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0084

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OTSUKA MARYLAND MEDICINAL LABORATORIES INC
9900 MEDICAL CENTER DRIVE

ROCKVILLE, MD 20850

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		26-NOV-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0086

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

FROSTBURG STATE UNIVERSITY
101 BRADDOCK ROAD

FROSTBURG, MD 21532

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	12	0	0	12
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	0	650	0	650

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		12-DEC-2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0086

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

FROSTBURG STATE UNIVERSITY
101 BRADDOCK ROAD

FROSTBURG, MD 21532

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
WHITE FOOTED MICE	0	0	31	0	31
SOUTHERN FLYING SQUIRRELS	0	0	7	0	7
EASTERN CHIPMUNKS	0	0	3	0	3
RED BACKED VOLES	0	0	2	0	2
TOMES SPINY RATS	0	0	397	0	397
ARMORED RATS	0	0	129	0	129
COMMON OPOSSUMS	0	0	47	0	47
ROBINSONS MOUSE OPOSSUMS	0	0	20	0	20
ALSTONS MOUSE OPOSSUMS	0	0	2	0	2
BICOLORED ARBOREAL RICE RATS	0	0	3	0	3
BROWN FOUR EYED OPOSSUMS	0	0	1	0	1
CENTRAL AMERICAN AGOUTIS	0	0	1	0	1
RED TAILED SQUIRRELS	0	0	7	0	7

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
12-DEC-2013

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0087

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

GENVEC INC
910 CLOPPER RD
SUITE 220 N
GAITHERSBURG, MD 20878

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-FEB-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0087

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

GENVEC INC
910 CLOPPER RD
SUITE 220 N
GAITHERSBURG, MD 20878

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
NEW ALL ANIMAL	0	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c) [redacted]

DATE SIGNED
03-FEB-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0089

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

AVANZA LABORATORIES LLC
11 FIRSTFIELD ROAD
SUITE B
GAITHERSBURG, MD 20878

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	168	35	0	203
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	42	0	0	42
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		26-NOV-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0090

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

TACONIC FARMS INC
7676 STANDISH PLACE

ROCKVILLE, MD 20855

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	2	0	0	2
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	3	0	0	3

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		29-NOV-2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0090

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

TACONIC FARMS INC
7676 STANDISH PLACE

ROCKVILLE, MD 20855

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	3	0	0	3

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
29-NOV-2013

APHIS FORM 7023A
AUG 2013

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0091

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SIGMOVIR BIOSYSTEMS INC
9610 MEDICAL CENTER DRIVE SUITE 100

ROCKVILLE, MD 20850

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	962	843	0	0	843

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		12-DEC-2013

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0091

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SIGMOVIR BIOSYSTEMS INC
9610 MEDICAL CENTER DRIVE SUITE 100

ROCKVILLE, MD 20850

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
COTTON RATS	962	843	0	0	843

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
12-DEC-2013

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0093

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SO BRAN INC
4000 BLACKBURN LANE SUITE 100

BURTONSVILLE, MD 20866

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		11-DEC-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0095

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF MARYLAND COLLEGE PARK
DIRECTOR LABORATORY ANIMAL CARE
COLLEGE PARK CAMPUS
COLLEGE PARK, MD 20742

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	11	12	0	23
7. Hamsters	0	0	12	0	12
8. Rabbits	0	0	14	0	14
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	270	658	112	80	850

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		18-FEB-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0095

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

UNIVERSITY OF MARYLAND COLLEGE PARK
DIRECTOR LABORATORY ANIMAL CARE
COLLEGE PARK CAMPUS
COLLEGE PARK, MD 20742

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	31	100	80	211
BATS	192	380	10	0	390
GRAY SQUIRRELS	0	200	0	0	200
DEER MICE	78	47	2	0	49

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
18-FEB-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0096

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

LOYOLA UNIVERSITY MARYLAND
BIOLOGY DEPARTMENT
4501 N CHARLES ST
BALTIMORE, MD 21210

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	70	242	0	0	242

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-FEB-2014

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0096

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

LOYOLA UNIVERSITY MARYLAND
BIOLOGY DEPARTMENT
4501 N CHARLES ST
BALTIMORE, MD 21210

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
DEER MICE	30	80	0	0	80
CALIFORNIA MICE	40	162	0	0	162

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED
03-FEB-2014

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0097

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

SMITHERS AVANZA TOXICOLOGY SERVICES LLC
11 B FIRST FIELD RD

GAITHERSBURG, MD 20878

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	36	47	0	83
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	12	0	0	12
7. Hamsters	0	0	0	0	0
8. Rabbits	0	296	2	0	298
9. Non-human Primates	36	66	58	0	124
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-R-0098

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

I 2 L RESEARCH U S A INC
1330 DILLON HEIGHTS AVENUE

BALTIMORE, MD 21228

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	10	0	0	10
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		12-DEC-2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-V-0010

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

VA MEDICAL CENTER
RESEARCH SERVICE (151)
10 NORTH GREENE STREET
BALTIMORE, MD 21201

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)(c)		03-FEB-2014

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 10-F-0002

2. Number of animals used in this study: 498

3. Species (common name) of animals used in the study: **Guinea Pig**

4. Explain the procedure (the cause of the pain) producing pain and/or distress:

The pain is a result of an infection in the eye after inoculation with Shigella species. The infection causes a mild to severe keratoconjuctivitis.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress would interfere with test results. (For Federally mandated testing, see item 6 below):

The study of the immune response to and protective efficacy of vaccine candidates directed against shigellae, which are the primary goal of the MRMC, requires an accurate evaluation of the immune response raised by the administration of these vaccines. The use of analgesics, particularly opiates or narcotics, result in the immunosupression (see Einstein et el, 1993, Pruett, 1992, and Einstein 1998), which would invalidate the results of experiments testing immune responses as well as increasing the severity of the possible eye infection, since immunized animals frequently develop either mild infection or no infection at all. Analgesics such as aspirin or ibuprofen are anti-inflammatory, and since the *keratoconjunctivits* is largely a result of epithelial cell inflammation due to bacterial invasion, the use of such anti-inflammatory agents would also invalidate the model. It is not known how analgesics would affect the protective capacity of Shigella vaccines.

Two additional publications (Swearengen et al, 1993; Hanson et al, 2001) have studied the effects of analgesics (buprenophrine) on the Sereny test. These studies have shown that the use of analgesics increases the purulence and crustiness of Shigella-infected eyes, probably due to the lethargy of the animals that prevented normal grooming habits (Swearengen et al, 1993). Scoring of eyes crusted shut is very difficult because the eyes are glued shut by exudates, a problem not normally encountered. This problem complicates the interpretation of the reaction and therefore assessment of the virulence of shigellae. As the discharge is part of the Hartman scoring system (Hartman et al, 1991), which we have used for over 18 years, an increase in discharge will lead to artificially high scores that may lead to a

misinterpretation of the virulence of a wild-type Shigella strain, the misinterpretation of the safety (lack of reactogenicity) of a live-attenuated vaccine strain, and finally the misinterpretation of a vaccine's efficacy. The possible enhanced immune response in buprenophrine-treated animals could lead to misinterpretation of the immunogenicity and efficacy of experimental vaccines.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: _____ CFR: _____

Column E Explanation

1. Registration Number: Armed Forces Radiobiology Research Institute, Certificate #51-F-0003

2. Number of animals used in this study: 4

3. Species (common name) of animals used in the study: Pigs

4. Explain the procedure producing pain and/or distress.

   The Gottingen minipig is being used to develop a model for radiation-induced multi-organ failure. To gather sufficient information, animals will be exposed to lethal and sublethal doses of whole-body gamma radiation (0.6 Gy/min) utilizing the cobalt facility. The gray (symbol: Gy) is the SI unit of absorbed radiation dose of ionizing radiation (for example, X-rays), and is defined as the absorption of one joule of ionizing radiation by one kilogram of matter (usually human tissue).

   Irradiation itself is not a painful process but it induces various changes in the body (i.e., vomiting and nausea, changes in hematology cells numbers, etc.). Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of sequelae. Radiation compromises the immune system. As a result of a compromised immune response, various types of infections can initiate and become painful. The sequelae of nausea, vomiting, and diarrhea may cause pain and distress as observed in humans in the early post-irradiation period, when lethal doses are used.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   To study the efficacy of any radiation countermeasure in modulating survival, and to investigate its mechanism of action, one needs to irradiate animals. Irradiation itself is not a painful process; in fact, it can be analgesic (Teskey, G. C., and M. Kavaliers. 1984. Ionizing radiation induces opioid-mediated analgesia in male mice. Life Sci 35:1547-1552), but it induces various changes in the body, and kills hematopoietic and other radiosensitive cells. In irradiated animals, the immune response is compromised, and opportunistic infections may ensue.

   Irradiated animals die due to compromised immune responses and opportunistic infections. The percentage of surviving animals is the indicator of the efficacy of a countermeasure. We cannot give systemic anesthetic and/or analgesic agents to animals after the irradiation procedures, since they are known to interact with the immune system (Jacobsen, K. 0., V. Villa, V. L. Miner, and M. H. Whitnall. 2004. Effects of anesthesia and vehicle injection on circulating blood elements in C3H/HeN male mice. Contemp Top Lab Anim Sci 43:8-12), and would confound the correlation of radiation dose with incidence of moribundity, resulting in a waste of animals.

   The endpoint currently mandated by the FDA for approval of radiation countermeasures under the Animal Efficacy Rule is mortality. Hence the primary endpoint in our development of Gottingen minipigs as a model for ARS is survival. Moribundity will be used as a surrogate for mortality, and euthanasia will be used in order to minimize pain and distress, using an extensive set of criteria.

Column E Explanation

1. Registration Number: Armed Forces Radiobiology Research Institute, Certificate #51-F-0003

2. Number of animals used in this study: 28 (Study A) and 28 (Study B)

3. Species (common name) of animals used in the study: Non-human Primates

4. Explain the procedure producing pain and/or distress.

   To evaluate the pharmacokinetics of GT3 as well as the efficacy of GT3 in enhancing survival of irradiated NHPs (Study A) and to evaluate the efficacy of ALXN4100TPO in enhancing survival of irradiated NHPs (Study B) the animals must be exposed to whole-body gamma radiation (0.6 Gy/min) utilizing the cobalt facility. The gray (symbol: Gy) is the SI unit of absorbed radiation dose of ionizing radiation (for example, X-rays), and is defined as the absorption of one joule of ionizing radiation by one kilogram of matter (usually human tissue).

   There are no alternative procedures for irradiation because it is a unique stimulus/stress that cannot be otherwise duplicated. Radiation itself does not cause pain or distress. Nevertheless, the sequelae of nausea, vomiting, and diarrhea causes pain and distress, as seen in humans in the early post-irradiation period, when high doses are used. Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of hematological and gastro-intestinal damage.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   Study A and B: It is expected that GT3 (Study A) or ALXN4100TPO (Study B) will provide some relief from pain and or discomfort due to the sequelae of irradiation by its protective effect and by the possibility that it will advance hematopoietic recovery in some or all of the GT3-treated and irradiated primates (Study A) or ALXN4100TPO-treated and irradiated primates (Study B). Along these lines, opioid analgesics are immunomodulatory (Pruett *et al,* 1992, Pasotti *et al,* 1993, Carr *et al,* 1994) and will not be used to relieve pain or distress. Non-narcotic analgesics such as indomethacin are anti-inflammatory and could interfere with the inflammatory responses of the antibacterial activity of hematopoietic tissues. Analgesics cause adverse effects on undamaged hematopoietic cells, (Hollaender, 1960) and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH+ oxidase), a key polymorphonuclear leukocyte enzyme that is involved in the ability of the cells to undergo phagocytosis of bacteria (Moon *et al,* 1986). Because of these observations, we do not intend to use analgesics as they will interfere with the purpose of the research effort. Moribundity will be used as a surrogate for mortality, and euthanasia will be used in order to minimize pain and distress, using an extensive set of criteria.

   References:

Carr DJ, Gerak LR, and France CP (1994). Maltrexone antagonizes the analgesic and immunosuppressive effects of morphine in mice. "J. Pharmacol. Exp. Ther". **269**:693-698.

Hollaneder A., 1960, *Radiation Protection and Recovery,* 1-392 (Pergamon Press, New York).

Moon, B.C., M.J. Girotti, S.G.F. Wren, R. Dawson, (1986). Effect of antibiotics and sedatives on normal neutrophil nicotinamide adenine dinucleotide phosphate-reduce oxidase activity. "Arch. Surg." **121**: 673-76.

Pasotti, D., A. Mazzone, S. Lecchini, G.M. Frigo, and G. Ricevuti (1993). Influenza dei peptidi oppioidi sui granulociti del sangue periferico. [The effect of opioid peptides on peripheral blood granulocytes.] "Riv. Eur. Sci. Med. Farmacol" **15**: 71-81.

Pruett S.B, Han JC, Fuchs BA (1992). Morphine suppresses primary humoral immune response by a predominantly indirect mechanism. "J. Pharmacol. Exp. Ther". **262**:923-928.

Column E Explanation

1. Registration Number: Armed Forces Radiobiology Research Institute, Certificate #51-F-0003

2. Number of animals used in this study: 2

3. Species (common name) of animals used in the study: Non-human Primates

4. Explain the procedure producing pain and/or distress.

   Animals must be exposed to whole-body gamma radiation (0.6 Gy/min) utilizing the cobalt facility in order to study biodosimetric endpoints using a NHP radiation dose-response model, and to investigate the correlation between these endpoints and dose, acute radiation syndrome (ARS) response severity response, and survival. The gray (symbol: Gy) is the SI unit of absorbed radiation dose of ionizing radiation (for example, X-rays), and is defined as the absorption of one joule of ionizing radiation by one kilogram of matter (usually human tissue).

   There are no alternative procedures for irradiation because it is a unique stimulus/stress that cannot be otherwise duplicated. Irradiation itself is not a painful process but it induces various changes in the body (i.e., vomiting and nausea, changes in hematology cell counts, etc.). Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of sequelae. Radiation compromises the immune system. As a result of a compromised immune response, various types of infections can initiate and become painful. The sequelae of nausea, vomiting, and diarrhea may cause pain and distress as observed in humans observed in the early post-irradiation period, when lethal doses are used.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   These studies are scientifically justified based on the national interest to identify, optimize, and validate FDA-approved biodosimetry devices for potential radiological threats including mass-casualty incidences.

   Multiple blood protein biomarkers along with hematological surrogates will provide enhanced diagnostically useful indices to discriminate between injured and irradiated individuals. A panel of protein biomarkers, each with different radiation responses, coupled with peripheral blood cell counts or hematology surrogates will provide accurate assessment as well as an enhanced discrimination index of radiation exposure. Most studies will involve total-body irradiation (TBI) exposures to graded doses of gamma rays and the use of a minimum supportive care therapy model (including antiemetic, antidiarrheal, analgesics, oral fluid supplements etc) reflecting the anticipated limited medical-care situation in the early-phase of a mass-casualty radiological incident. In the early phase of mass-causality, intensive treatment options may not be available. A pilot high-dose discovery study will be performed to identify and develop new biomarkers. A treatment experiment will be completed to characterize the influence of cytokine and conventional treatment (antibiotics, analgesics, IV fluids or whole blood transfusion etc.) on candidate biomarkers simulating a more intensive treatment that would be available in a hospital. The conventional treatment supportive care therapy approach will be used that will include more aggressive therapy, included pain relief, similar to current treatment practice to characterize any effects of these treatments on the radiation biomarkers profile. In both arms of this study, animals are humanely euthanized when unrelieved pain and distress occurs, using an extensive set of clinical criteria.

Column E Explanation

1. Registration Number: Armed Forces Radiobiology Research Institute, Certificate #51-F-0003

2. Number of animals used in this study: 4

3. Species (common name) of animals used in the study: Pigs

4. Explain the procedure producing pain and/or distress.

   The Gottingen minipig is being used to develop a model for radiation-induced multi-organ failure. To gather sufficient information, animals will be exposed to lethal and sublethal doses of whole-body gamma radiation (0.6 Gy/min) utilizing the cobalt facility. The gray (symbol: Gy) is the SI unit of absorbed radiation dose of ionizing radiation (for example, X-rays), and is defined as the absorption of one joule of ionizing radiation by one kilogram of matter (usually human tissue).

   Irradiation itself is not a painful process but it induces various changes in the body (i.e., vomiting and nausea, changes in hematology cells numbers, etc.). Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of sequelae. Radiation compromises the immune system. As a result of a compromised immune response, various types of infections can initiate and become painful. The sequelae of nausea, vomiting, and diarrhea may cause pain and distress as observed in humans in the early post-irradiation period, when lethal doses are used.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   To study the efficacy of any radiation countermeasure in modulating survival, and to investigate its mechanism of action, one needs to irradiate animals. Irradiation itself is not a painful process; in fact, it can be analgesic (Teskey, G. C., and M. Kavaliers. 1984. Ionizing radiation induces opioid-mediated analgesia in male mice. Life Sci 35:1547-1552), but it induces various changes in the body, and kills hematopoietic and other radiosensitive cells. In irradiated animals, the immune response is compromised, and opportunistic infections may ensue.

   Irradiated animals die due to compromised immune responses and opportunistic infections. The percentage of surviving animals is the indicator of the efficacy of a countermeasure. We cannot give systemic anesthetic and/or analgesic agents to animals after the irradiation procedures, since they are known to interact with the immune system (Jacobsen, K. 0., V. Villa, V. L. Miner, and M. H. Whitnall. 2004. Effects of anesthesia and vehicle injection on circulating blood elements in C3H/HeN male mice. Contemp Top Lab Anim Sci 43:8-12), and would confound the correlation of radiation dose with incidence of moribundity, resulting in a waste of animals.

   The endpoint currently mandated by the FDA for approval of radiation countermeasures under the Animal Efficacy Rule is mortality. Hence the primary endpoint in our development of Gottingen minipigs as a model for ARS is survival. Moribundity will be used as a surrogate for mortality, and euthanasia will be used in order to minimize pain and distress, using an extensive set of criteria.

Column E Explanation

1. Registration Number: Armed Forces Radiobiology Research Institute, Certificate #51-F-0003

2. Number of animals used in this study: 28 (Study A) and 28 (Study B)

3. Species (common name) of animals used in the study: Non-human Primates

4. Explain the procedure producing pain and/or distress.

   To evaluate the pharmacokinetics of GT3 as well as the efficacy of GT3 in enhancing survival of irradiated NHPs (Study A) and to evaluate the efficacy of ALXN4100TPO in enhancing survival of irradiated NHPs (Study B) the animals must be exposed to whole-body gamma radiation (0.6 Gy/min) utilizing the cobalt facility. The gray (symbol: Gy) is the SI unit of absorbed radiation dose of ionizing radiation (for example, X-rays), and is defined as the absorption of one joule of ionizing radiation by one kilogram of matter (usually human tissue).

   There are no alternative procedures for irradiation because it is a unique stimulus/stress that cannot be otherwise duplicated. Radiation itself does not cause pain or distress. Nevertheless, the sequelae of nausea, vomiting, and diarrhea causes pain and distress, as seen in humans in the early post-irradiation period, when high doses are used. Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of hematological and gastro-intestinal damage.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   Study A and B: It is expected that GT3 (Study A) or ALXN4100TPO (Study B) will provide some relief from pain and or discomfort due to the sequelae of irradiation by its protective effect and by the possibility that it will advance hematopoietic recovery in some or all of the GT3-treated and irradiated primates (Study A) or ALXN4100TPO-treated and irradiated primates (Study B). Along these lines, opioid analgesics are immunomodulatory (Pruett *et al,* 1992, Pasotti *et al,* 1993, Carr *et al,* 1994) and will not be used to relieve pain or distress. Non-narcotic analgesics such as indomethacin are anti-inflammatory and could interfere with the inflammatory responses of the antibacterial activity of hematopoietic tissues. Analgesics cause adverse effects on undamaged hematopoietic cells, (Hollaender, 1960) and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH+ oxidase), a key polymorphonuclear leukocyte enzyme that is involved in the ability of the cells to undergo phagocytosis of bacteria (Moon *et al,* 1986). Because of these observations, we do not intend to use analgesics as they will interfere with the purpose of the research effort. Moribundity will be used as a surrogate for mortality, and euthanasia will be used in order to minimize pain and distress, using an extensive set of criteria.

   References:

Carr DJ, Gerak LR, and France CP (1994). Maltrexone antagonizes the analgesic and immunosuppressive effects of morphine in mice. "J. Pharmacol. Exp. Ther". **269**:693-698.

Hollaneder A., 1960, *Radiation Protection and Recovery,* 1-392 (Pergamon Press, New York).

Moon, B.C., M.J. Girotti, S.G.F. Wren, R. Dawson, (1986). Effect of antibiotics and sedatives on normal neutrophil nicotinamide adenine dinucleotide phosphate-reduce oxidase activity. "Arch. Surg." **121**: 673-76.

Pasotti, D., A. Mazzone, S. Lecchini, G.M. Frigo, and G. Ricevuti (1993). Influenza dei peptidi oppioidi sui granulociti del sangue periferico. [The effect of opioid peptides on peripheral blood granulocytes.] "Riv. Eur. Sci. Med. Farmacol" **15**: 71-81.

Pruett S.B, Han JC, Fuchs BA (1992). Morphine suppresses primary humoral immune response by a predominantly indirect mechanism. "J. Pharmacol. Exp. Ther". **262**:923-928.

Column E Explanation

1. Registration Number: Armed Forces Radiobiology Research Institute, Certificate #51-F-0003

2. Number of animals used in this study: 2

3. Species (common name) of animals used in the study: Non-human Primates

4. Explain the procedure producing pain and/or distress.

   Animals must be exposed to whole-body gamma radiation (0.6 Gy/min) utilizing the cobalt facility in order to study biodosimetric endpoints using a NHP radiation dose-response model, and to investigate the correlation between these endpoints and dose, acute radiation syndrome (ARS) response severity response, and survival. The gray (symbol: Gy) is the SI unit of absorbed radiation dose of ionizing radiation (for example, X-rays), and is defined as the absorption of one joule of ionizing radiation by one kilogram of matter (usually human tissue).

   There are no alternative procedures for irradiation because it is a unique stimulus/stress that cannot be otherwise duplicated. Irradiation itself is not a painful process but it induces various changes in the body (i.e., vomiting and nausea, changes in hematology cell counts, etc.). Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of sequelae. Radiation compromises the immune system. As a result of a compromised immune response, various types of infections can initiate and become painful. The sequelae of nausea, vomiting, and diarrhea may cause pain and distress as observed in humans observed in the early post-irradiation period, when lethal doses are used.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   These studies are scientifically justified based on the national interest to identify, optimize, and validate FDA-approved biodosimetry devices for potential radiological threats including mass-casualty incidences.

   Multiple blood protein biomarkers along with hematological surrogates will provide enhanced diagnostically useful indices to discriminate between injured and irradiated individuals. A panel of protein biomarkers, each with different radiation responses, coupled with peripheral blood cell counts or hematology surrogates will provide accurate assessment as well as an enhanced discrimination index of radiation exposure. Most studies will involve total-body irradiation (TBI) exposures to graded doses of gamma rays and the use of a minimum supportive care therapy model (including antiemetic, antidiarrheal, analgesics, oral fluid supplements etc) reflecting the anticipated limited medical-care situation in the early-phase of a mass-casualty radiological incident. In the early phase of mass-causality, intensive treatment options may not be available. A pilot high-dose discovery study will be performed to identify and develop new biomarkers. A treatment experiment will be completed to characterize the influence of cytokine and conventional treatment (antibiotics, analgesics, IV fluids or whole blood transfusion etc.) on candidate biomarkers simulating a more intensive treatment that would be available in a hospital. The conventional treatment supportive care therapy approach will be used that will include more aggressive therapy, included pain relief, similar to current treatment practice to characterize any effects of these treatments on the radiation biomarkers profile. In both arms of this study, animals are humanely euthanized when unrelieved pain and distress occurs, using an extensive set of clinical criteria.

FY2013 APHIS Form 7023 Column E Explanation

1. Registration Number: 51-F-0005

2. Species (common name) of animals used in the study:
   Sheep

3. Number of animals used in this study (in this pain category):
   1

4. Explain the procedure producing pain and/or distress.

Sheep were exposed during the method development phase of an inhalation study to a test concentration not expected to cause more than momentary pain or distress. However, one sheep experienced unanticipated respiratory compromise during the inhalation procedure so this one sheep was categorized as E.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

Based on a comparison of existing data from a similar inhalation toxicology test with phosgene, the duration and concentration of test material delivered to the sheep was not expected to cause unalleviated pain or distress. This was a single, unanticipated event and no other animals were category E.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

N/A

FY2013 APHIS Form 7023 Column E Explanation

1. Registration Number: 51-F-0005

2. Species (common name) of animals used in the study:
   Sheep

3. Number of animals used in this study (in this pain category):
   1

4. Explain the procedure producing pain and/or distress.

Sheep were exposed during the method development phase of an inhalation study to a test concentration not expected to cause more than momentary pain or distress. However, one sheep experienced unanticipated respiratory compromise during the inhalation procedure so this one sheep was categorized as E.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

Based on a comparison of existing data from a similar inhalation toxicology test with phosgene, the duration and concentration of test material delivered to the sheep was not expected to cause unalleviated pain or distress. This was a single, unanticipated event and no other animals were category E.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

N/A

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 8 hamsters, 9 guinea pigs**

3. **Species (common name) of animals used in this study:**
   Cavia porcellus (Hartley guinea pig)
   Mesocricetus auratus (Syrian golden hamster)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

After the adaptation processes, Marburg virus (MARV) causes lethal disease in guinea pigs and hamsters which closely mimics the hemorrhagic fever syndrome observed in humans infected with MARV. A mouse model is also available; however, the disease in the mouse differs in several aspects from human disease. Therefore, additional lethal small rodent models would be extremely beneficial to study pathogenesis and concepts for vaccination and therapies. This will further our understanding and help to reduce the use of nonhuman primates the ultimate disease model.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

The development of small animal disease models for MARV is essential for studying pathogenesis as well as the development of vaccines and anti-virals. The potential illness experienced by the some of the animals exposed to MARV must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.
During the passage experiments for obtaining lethal variants of MARV, it is impossible to predict the outcomes of these studies and especially the severity of disease associated with individual agents in the guinea pigs and hamsters. Animals will be scored daily according to an approved scoring sheet and will be euthanized when they reach a point where recovery seems unlikely to reduce suffering. There will be a conscious effort by all investigators and the animal care personnel to provide as much additional consideration for the comfort and wellbeing of the animals as is consistent with the scientific integrity of the protocol.

1. Hung CY, Lefkowitz SS, Geber WF. 1973. Interferon inhibition by narcotic analgesics. Proc Soc Exp Biol Med 142: 106-111.
2. Geber WF, Lefkowitz SS, Hung CY. 1977. Duration of interferon inhibition following single and multiple injections of morphine. J Toxicol Environ Health 2: 577-582.
3. Beilin B, Martin FC, Shavit Y, Gale RP, Liebeskind JC. 1989. Suppression of natural killer cell activity by high-dose narcotic anesthesia in rats. Brain Behav Immun 3: 129-137.
4. Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.
5. Marone G, Stellato C, Mastronardi P, Mazzarella B. 1993. Mechanisms of activation of human mast cells and basophils by general anesthetic drugs. Ann Fr Anesth Reanim 12: 116-125.

6. Soma LR. 1983. Anesthetic and analgesic considerations in the experimental animal. Ann NY Acad Sci 406: 32-47.
7. Marone G, Gentile M, Petraroli A, De Rosa N, Triggiani M. 2001. Histamine-induced activation of human lung macrophages. Int Arch Allergy Immunol 124: 249-252.
8. Mazzoni A, Leifer CA, Mullen GE, Kennedy MN, Klinman DM, Segal DM. 2003. Cutting edge: Histamine inhibits IFN-alpha release from plasmacytoid dendritic cells. J Immunol 170: 2269-2273.
9. Sirois J, Menard G, Moses AS, Bissonnette EY. 2000. Importance of histamine in the cytokine network in the lung through H2 and H3 receptors: stimulation of IL-10 production. J Immunol 164: 2964-2970.
10. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 12**

3. **Species (common name) of animals used in this study:**
Mesocricetus auratus (Syrian golden hamster)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

It is unknown whether Zaire Ebola Virus (ZEBOV) will cause disease in T cell-depleted hamsters. In order to develop and characterize the immune response in animal models mimicking VHFs in humans, hamsters will be used.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

The illness experienced by the animals exposed to the VHF viruses indicated below must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 4**

3. **Species (common name) of animals used in this study:** *Cavia porcellus* (Guinea pigs, Hartley & Strain 13)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

Experimental manipulations will be done on anaesthetized animals. Guinea pigs are susceptible to infection with Lujo virus; however only mild signs of infection are apparent following infection with wild-type virus (Safronetz, Feldmann unpublished data). The majority of animals in this study will be euthanized prior to the onset of terminal signs of disease (as a part of the serial passaging process). During serial passage of Lujo virus through Guinea pigs it is expected that the virus will acquire mutations allowing it to evade the host immune responses and replicate more efficiently in a variety of tissues. As these mutations accumulate we expect to observe clinical signs of disease that may include lethargy, increased weight loss, hemorrhage, respiratory distress and neurological disorders, which ultimately might be fatal. Also, guinea pigs have already been successfully used to develop a lethal disease model of Lassa virus, a close relative of Lujo virus.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

Since the aim of these experiments is to lethally adapt Lujo virus to inbred and outbred Guinea pigs, we are unable to alleviate these potential signs of disease because treatment will interfere with the adaption process / disease manifestations and ultimate outcomes of infection. The use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.

1. Hung CY, Lefkowitz SS, Geber WF. 1973. Interferon inhibition by narcotic analgesics. Proc Soc Exp Biol Med 142: 106-111.
2. Geber WF, Lefkowitz SS, Hung CY. 1977. Duration of interferon inhibition following single and multiple injections of morphine. J Toxicol Environ Health 2: 577-582.
3. Beilin B, Martin FC, Shavit Y, Gale RP, Liebeskind JC. 1989. Suppression of natural killer cell activity by high-dose narcotic anesthesia in rats. Brain Behav Immun 3: 129-137.
4. Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.
5. Marone G, Stellato C, Mastronardi P, Mazzarella B. 1993. Mechanisms of activation of human mast cells and basophils by general anesthetic drugs. Ann Fr Anesth Reanim 12: 116-125.
6. Soma LR. 1983. Anesthetic and analgesic considerations in the experimental animal. Ann NY Acad Sci 406: 32-47.
7. Marone G, Gentile M, Petraroli A, De Rosa N, Triggiani M. 2001. Histamine-induced activation of human lung macrophages. Int Arch Allergy Immunol 124: 249-252.
8. Mazzoni A, Leifer CA, Mullen GE, Kennedy MN, Klinman DM, Segal DM. 2003. Cutting edge: Histamine inhibits IFN-alpha release from plasmacytoid dendritic cells. J Immunol 170: 2269-2273.

9. Sirois J, Menard G, Moses AS, Bissonnette EY. 2000. Importance of histamine in the cytokine network in the lung through H2 and H3 receptors: stimulation of IL-10 production. J Immunol 164: 2964-2970.
10. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 14**

3. **Species (common name) of animals used in this study: Guinea pigs (Cavia porcellus)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** *(from ASP Section*

Currently Guinea pigs are the only small animal model described for Lassa fever. In these studies we will be using two Lassa virus strains, one which has been adapted to outbred Guinea pigs and the parental Lassa virus strain which infects Guinea pigs but is not uniformly lethal. Infected animals demonstrate signs of disease which can include weight loss, ruffled fur, labored breathing and hemorrhagic manifestations which are ultimately lethal in 30% (for wild-type Lassa virus Josiah) or 100% (for Guinea-pig adapted Lassa virus Josiah) of Guinea pigs. The purpose of this work is to characterize the outbred Guinea pig model for Lassa virus infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

In these experiments Guinea pigs will be infected with a challenge dose of Lassa virus which has previously been determined to cause lethal disease in 30 - 100% of animals (dependent on the strain of Lassa virus utilized). Following challenge, infected animals will appear normal until around 5-7 days, after which they may demonstrate signs of disease including weight loss, ruffled fur and lethargy. The purpose of these studies is to compare the disease progression associated with infection of two Lassa virus strains in Guinea-pigs. Animals will be euthanized at scheduled time points or when signs of advanced disease are apparent. Health status of individual animals will be assessed according to a numerical scoring index as follows: 0 = no signs; 1 = ruffled fur ; 2 = ruffled fur & weight loss <5%; 3 = ruffled fur, hunched posture & weight loss > 5%; 4 = ruffled fur, hunched posture & weight loss > 10%; 5 = ruffled fur, hunched posture, weight loss > 15% or paralysis of limbs or hemorrhagic manifestations or dyspnea; 6 = ruffled fur, hunched posture, weight loss > 20% or paralysis of limbs or hemorrhagic manifestations or dyspnea; 7 = death. Animals will be euthanized if they reach a score $\geq$ 5, or at 45 days post infection. We are unable to alleviate signs of disease in these animals since the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process, which is hypothesized to be important in HPS disease progression. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.

1. Hung CY, Lefkowitz SS, Geber WF. 1973. Interferon inhibition by narcotic analgesics. Proc Soc Exp Biol Med 142: 106-111.
2. Geber WF, Lefkowitz SS, Hung CY. 1977. Duration of interferon inhibition following single and multiple injections of morphine. J Toxicol Environ Health 2: 577-582.
3. Beilin B, Martin FC, Shavit Y, Gale RP, Liebeskind JC. 1989. Suppression of natural killer cell activity by high-dose narcotic anesthesia in rats. Brain Behav Immun 3: 129-137.
4. Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.
5. Marone G, Stellato C, Mastronardi P, Mazzarella B. 1993. Mechanisms of activation of human mast cells and basophils by general anesthetic drugs. Ann Fr Anesth Reanim 12: 116-125.

6. Soma LR. 1983. Anesthetic and analgesic considerations in the experimental animal. Ann NY Acad Sci 406: 32-47.
7. Mazzoni A, Leifer CA, Mullen GE, Kennedy MN, Klinman DM, Segal DM. 2003. Cutting edge: Histamine inhibits IFN-alpha release from plasmacytoid dendritic cells. J Immunol 170: 2269-2273.
8. Marone G, Gentile M, Petraroli A, De Rosa N, Triggiani M. 2001. Histamine-induced activation of human lung macrophages. Int Arch Allergy Immunol 124: 249-252.
9. Sirois J, Menard G, Moses AS, Bissonnette EY. 2000. Importance of histamine in the cytokine network in the lung through H2 and H3 receptors: stimulation of IL-10 production. J Immunol 164: 2964-2970.
10. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 4

3. Species (common name) of animals used in this study: Cynomolgus macaques (*Macaca fascicularis*)

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected. *(from ASP Section F)*

The challenge dose of Lassa virus which will be administered in these studies has previously been shown to result in severe infection with a lethal outcome in naïve nonhuman primates. Cynomolgus macaques are susceptible to Lujo and Lassa virus infections therefore are the most appropriate species for these studies. The veterinary staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are seen: dyspnea, anorexia, paralysis, unable to move from the ground of the cage, and severe weight loss (>20%). The animals will be euthanized at the specified time points or when clinical disease progression is considered irreversible (based on the clinical evaluation by the veterinarian).

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. *(from ASP, Section F)*

We have established a scoring system that will assist us in determining the humane end point for euthanasia. Animals challenged with Lassa virus may experience pain and distress and the infection may even be lethal, however the results of literature searches suggest treatment of pain / distress will interfere with the goals of this study. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target systems that are being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. The illness experienced by the Lassa infected animals must not be treated because treatment will interfere with studying the pathogenesis of the disease and identifying potential correlates of immunity. Importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.

1 Hung CY, Lefkowitz SS, Geber WF. 1973. Interferon inhibition by narcotic analgesics. Proc Soc Exp Biol Med 142: 106-111.

2 Geber WF, Lefkowitz SS, Hung CY. 1977. Duration of interferon inhibition following single and multiple injections of morphine. J Toxicol Environ Health 2: 577-582.

3 Beilin B, Martin FC, Shavit Y, Gale RP, Liebeskind JC. 1989. Suppression of natural killer cell activity by high-dose narcotic anesthesia in rats. Brain Behav Immun 3: 129-137.

4 Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.

5 Marone G, Stellato C, Mastronardi P, Mazzarella B. 1993. Mechanisms of activation of human mast cells and basophils by general anesthetic drugs. Ann Fr Anesth Reanim 12: 116-125.

6 Soma LR. 1983. Anesthetic and analgesic considerations in the experimental animal. Ann NY Acad Sci 406: 32-47.

7 Mazzoni A, Leifer CA, Mullen GE, Kennedy MN, Klinman DM, Segal DM. 2003. Cutting edge: Histamine inhibits IFN-alpha release from plasmacytoid dendritic cells. J Immunol 170: 2269-2273.
8 Marone G, Gentile M, Petraroli A, De Rosa N, Triggiani M. 2001. Histamine-induced activation of human lung macrophages. Int Arch Allergy Immunol 124: 249-252.
9 Sirois J, Menard G, Moses AS, Bissonnette EY. 2000. Importance of histamine in the cytokine network in the lung through H2 and H3 receptors: stimulation of IL-10 production. J Immunol 164: 2964-2970.
10. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study:** 4

3. **Species (common name) of animals used in this study:** Cynomolgus macaques (*Macaca fascicularis*)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

Marburg virus causes significant disease, which is associated with distress in nonhuman primates. Causing infection in nonhuman primates is necessary in order to evaluate the efficacy of a vaccine. The investigator will notify the facility staff when animals begin the Column E study. The veterinary staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are seen: dyspnea, anorexia, paralysis, unable to move from the ground of the cage, and significant weight loss (>15%). The animals will be euthanized at the specified time points or when clinical disease progression is considered irreversible based on the clinical evaluation by the veterinarian in consultation with PI.

Animals infected with Marburg virus will experience pain and distress and the infection will be lethal in non-protected animals. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, and stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target organ systems that are being evaluated in this study. Opiates are not indicated since they have depressant effects on the cardiovascular and respiratory systems and could alter the parameters to be measured and even accelerate the pathology and death. Instead we have established a scoring system that will allow us to determine the humane end point for euthanasia. The illness experienced by the animals exposed to Marburg virus must not be treated with analgesics because such treatment will interfere with studying the pathogenesis of the disease. More importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to cause respiratory and cardiovascular depression. They also interfere with the mechanism(s) responsible for interferon production (1,2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics, including buprenorphine, can cause an histamine release and respiratory depression (4-6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process, which has to be considered as a critical component in the pathogenesis of Marburg virus. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids, fentanyl and buprenorphine, directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following the administration of LPS.

References:

11. Hung CY, Lefkowitz SS, Geber WF. 1973. Interferon inhibition by narcotic analgesics. Proc Soc Exp Biol Med 142: 106-111.
12. Geber WF, Lefkowitz SS, Hung CY. 1977. Duration of interferon inhibition following single and multiple injections of morphine. J Toxicol Environ Health 2: 577-582.
13. Beilin B, Martin FC, Shavit Y, Gale RP, Liebeskind JC. 1989. Suppression of natural killer cell activity by high-dose narcotic anesthesia in rats. Brain Behav Immun 3: 129-137.
14. Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.
15. Marone G, Stellato C, Mastronardi P, Mazzarella B. 1993. Mechanisms of activation of human mast cells and basophils by general anesthetic drugs. Ann Fr Anesth Reanim 12: 116-125.
16. Soma LR. 1983. Anesthetic and analgesic considerations in the experimental animal. Ann NY Acad Sci 406: 32-47.

17. Mazzoni A, Leifer CA, Mullen GE, Kennedy MN, Klinman DM, Segal DM. 2003. Cutting edge: Histamine inhibits IFN-alpha release from plasmacytoid dendritic cells. J Immunol 170: 2269-2273.
18. Marone G, Gentile M, Petraroli A, De Rosa N, Triggiani M. 2001. Histamine-induced activation of human lung macrophages. Int Arch Allergy Immunol 124: 249-252.
19. Sirois J, Menard G, Moses AS, Bissonnette EY. 2000. Importance of histamine in the cytokine network in the lung through H2 and H3 receptors: stimulation of IL-10 production. J Immunol 164: 2964-2970.
20. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. *(from ASP, Section F)*

Control and vaccinated/depleted animals challenged with Marburg virus may experience pain and distress and the infection may even be lethal. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target systems that are being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise, which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we have established a scoring system that will allow us to determine the humane end point for euthanasia.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 10**

3. **Species (common name) of animals used in this study: *Sus scrofa domestica* (domestic pig)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

Following inoculation of pigs with PRRSV, animals may develop signs of disease that could include lethargy, inappetence, labored breathing or swelling of joints. Recreating disease, and possibly serious disease, in pigs is necessary to understand pathogenesis of this virus and for the development of vaccines and antiviral treatments. To minimize pain and distress, the pigs will be checked twice daily beginning on day 1 of the study and any animals exhibiting clear signs of distress/pain will be euthanized after evaluation by the attending veterinarian and in consultation with the PI. All euthanasia procedures will be done by trained personnel.
Swine are the appropriate model to use in these experiments, since they are the natural host of PRRSV.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*
The refinement of the swine model for PRRSV is essential for studying pathogenesis as well as the development of vaccines and antivirals. The potential illness experienced by some of the animals exposed to PRRSV must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study.

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study:** 28 hamster and 30 guinea pigs

3. **Species (common name) of animals used in this study:** Guinea pigs and hamsters

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

After the adaptation processes, Marburg virus (MARV) will cause lethal disease in guinea pigs and hamsters which closely mimics the hemorrhagic fever syndrome observed in humans infected with MARV. A mouse model is also available; however, the disease in the mouse differs in several aspects from human disease. Therefore, additional lethal small rodent models would be extremely beneficial to study pathogenesis and concepts for vaccination and therapies. This will further our understanding and help to reduce the use of nonhuman primates the ultimate disease model.

The study endpoint is euthanasia at different time points for each experiment in this ASP as outlined in the corresponding paragraph in section F or at a time point when animals appear to be in an advanced stage of disease as determined in previous experiments with EBOV (weight loss >20%, dyspnea, and/or neurological signs).
The health of animals will be assessed daily according to the following criteria:
0 = no signs of disease; 1 = ruffled fur; 2 = ruffled fur & weight loss <5%; 3 = ruffled fur, hunched posture & weight loss > 5%; 4 = ruffled fur, hunched posture & weight loss > 10%; 5 = ruffled fur, hunched posture, weight loss > 15%; 6 = ruffled fur, hunched posture, weight loss > 20% or encephalitic signs or hemorrhagic signs or paralytic signs or respiratory distress (dyspnea); 7 = death. Euthanasia will occur at a score of 6.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

The development of small animal disease models for MARV is essential for studying pathogenesis as well as the development of vaccines and antivirals. The potential illness experienced by the some of the animals exposed to MARV must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.
During the passage experiments for obtaining lethal variants of MARV, it is impossible to predict the outcomes of these studies and especially the severity of disease associated with individual agents in the guinea pigs and hamsters. Animals will be scored daily as outlined above and will be euthanized when they reach a point where recovery seems unlikely to reduce suffering. There will be a conscious effort by all investigators and the animal care personnel to provide as much additional consideration for the comfort and well-being of the animals as is consistent with the scientific integrity of the protocol.

1. Hung CY, Lefkowitz SS, Geber WF. 1973. Interferon inhibition by narcotic analgesics. Proc Soc Exp Biol Med 142: 106-111.
2. Geber WF, Lefkowitz SS, Hung CY. 1977. Duration of interferon inhibition following single and multiple injections of morphine. J Toxicol Environ Health 2: 577-582.
3. Beilin B, Martin FC, Shavit Y, Gale RP, Liebeskind JC. 1989. Suppression of natural killer cell activity by high-dose narcotic anesthesia in rats. Brain Behav Immun 3: 129-137.

4. Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.
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7. Marone G, Gentile M, Petraroli A, De Rosa N, Triggiani M. 2001. Histamine-induced activation of human lung macrophages. Int Arch Allergy Immunol 124: 249-252.
8. Mazzoni A, Leifer CA, Mullen GE, Kennedy MN, Klinman DM, Segal DM. 2003. Cutting edge: Histamine inhibits IFN-alpha release from plasmacytoid dendritic cells. J Immunol 170: 2269-2273.
9. Sirois J, Menard G, Moses AS, Bissonnette EY. 2000. Importance of histamine in the cytokine network in the lung through H2 and H3 receptors: stimulation of IL-10 production. J Immunol 164: 2964-2970.
10. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 25**

3. **Species (common name) of animals used in this study:**
Ferret (*Mustela putorius furo)*

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

Pandemic H1N1 isolates may cause severe or lethal disease in ferrets which partially mimics the respiratory disease observed in humans infected with the virus. The seasonal and 2009 pandemic influenza a virus strain will likely cause limited morbidity or mortality compared to the 1918 H1N1 influenza A virus.

In general, different animal models are used to study pathogenesis, transmission and immune response to influenza virus infection including nonhuman primates, ferrets and mice. At present no alternatives are available to study these complex virus-host interactions.

The ferret is currently the best characterized and accepted small animal model of influenza pathogenicity studies.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

The illness experienced by the animals exposed to the human influenza A virus must not be treated with analgesics because treatment will interfere with the disease manifestation and study parameters such as innate immune responses, immunology and virology. In order to minimize pain and distress, animals will be clinically evaluated at least daily and will be euthanized if they reach a point of severe disease, or at 14 days post exposure.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 114**

3. **Species (common name) of animals used in this study: Syrian hamsters (Mesocricetus auratus)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (*from ASP Section F*):**
Andes virus causes lethal hantavirus pulmonary syndrome (HPS)-like disease in Syrian hamsters. Currently the Andes virus / hamster model of HPS is the only small animal model available for the study of hantavirus pathogenesis and potential therapeutics, therefore at this time it is the only model with which we can study the effect of preventing S1P receptor signaling on HPS development. Animals receiving S1P inhibitors will be euthanized if they appear to have entered the terminal stages of disease (i.e. respiratory distress). Control (vehicle treated) animals will be euthanized when respiratory distress become apparent.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results *(from ASP, Section F)*:**
In these experiments hamsters will be infected with a challenge dose of Andes virus which has previously been determined to cause lethal disease in 100% of animals. Following challenge, infected hamsters will appear normal until around 11 or 12 days post infection, after which they will demonstrate signs of disease including respiratory insufficiencies and death within approximately 24 hours. It is the goal of these studies to determine if blocking S1P receptor signaling can prevent or reduce mortality associated with lethal HPS disease in this animal model. As such, animals receiving S1P inhibitors will be euthanized if they appear to have entered the terminal stages of disease (i.e respiratory distress). Control (vehicle treated) animals will be euthanized when breathing insufficiencies become apparent. The use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production. Moreover, opioids can suppress NK cell activity. Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release and respiratory depression. Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages, inhibit interferon-alpha release from dendritic cells, and increase the synthesis and release of IL-10 from human macrophages. Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. In summary, alleviating the pain or discomfort with analgesics in treated hamsters could directly interfere with the disease progression of the virus and/or the immune mediated protection, thereby making the data collected impossible to interpret.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study:** 1 hamster

3. **Species (common name) of animals used in this study:**
Syrian hamsters (Mesocricetus auratus)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):**
Currently no animal models are available for the novel human coronavirus. Although no data is currently available on the novel coronavirus it can be anticipated that inoculation with the novel coronavirus will be associated with distress in hamsters and non-human primates. Hamsters inoculated with the novel coronavirus will be euthanized if they appear to have entered the terminal stages of disease (i.e. respiratory distress).

For the non-human primates, the veterinary staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are seen: dyspnea, anorexia, paralysis, unable to move from the ground of the cage, and significant weight loss (>15%). The animals will be euthanized at the specified time points or when clinical disease progression is considered irreversible (based on the clinical evaluation by the veterinarian in consultation with PI.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):**
Animals inoculated with the novel coronavirus may experience pain and distress and the infection may even be lethal. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target systems that are being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise, which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems.
We have established a scoring sheet that will allow us to determine the humane end point for euthanasia for the non-human primates.

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 12**

3. **Species (common name) of animals used in this study:**
Syrian hamsters (Mesocricetus auratus)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):**

Andes virus causes lethal hantavirus pulmonary syndrome (HPS)-like disease in Syrian hamsters. Currently the Andes virus / hamster model of HPS is the only small animal model available for the study of hantavirus pathogenesis and potential therapeutics, therefore at this time it is the only model with which we can study the effect of inhibiting specific host responses on HPS development. Animals receiving inhibitors will be euthanized if they appear to have entered the terminal stages of disease (i.e. respiratory distress). Control (vehicle treated) animals will be euthanized when breathing insufficiencies become apparent.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):**

In these experiments hamsters will be infected with a challenge dose of Andes virus which has previously been determined to cause lethal disease in 100% of animals. Following challenge, infected hamsters will appear normal until around 11 or 12 days post infection, after which they will demonstrate signs of disease including respiratory insufficiencies and death within approximately 24 hours. It is the goal of these studies to determine if blocking specific host responses can prevent or reduce mortality associated with lethal HPS disease in this animal model. As such, animals receiving inhibitors will be euthanized if they appear to have entered the terminal stages of disease (i.e respiratory distress). Control (vehicle treated) animals will be euthanized when breathing insufficiencies become apparent. The use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production. Moreover, opioids can suppress NK cell activity. Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release and respiratory depression. Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages, inhibit interferon-alpha release from dendritic cells, and increase the synthesis and release of IL-10 from human macrophages. Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. In summary, alleviating the pain or discomfort with analgesics in treated hamsters could directly interfere with the disease progression of the virus and/or the immune mediated protection, thereby making the data collected impossible to interpret.

Column E Explanation Form For Regulated Species

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1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 24

3. Species (common name) of animals used in this study: Syrian hamster

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):

Infection of hamsters with MA-ZEBOV could cause distress in immunocompetent animals As not all aspects of EBOV hemorrhagic fever, most notably coagulation disorders, are fully recapitulated in the mouse model, we propose to use the hamster model here instead. The hamster model does more accurately portray the disease syndrome.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):

Hamsters infected with MA-ZEBOV may experience pain and distress and the infection may be lethal. NSAIDs cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis as was stabilization of lysosomal membranes that may reduce the release of cytokines. In addition, certain classes of NSAIDs have been documented to reduce VSV replication – which could be extrapolated to affect ZEBOV replication. These affected systems are target systems being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we will use daily clinical evaluation that will allow us to determine the humane endpoint for euthanasia.

Recreating disease, and possibly serious disease, in these animals is necessary in order to test the efficacy of the treatments proposed. The investigator will notify the facility staff when animals begin the Column E study. The veterinary staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are observed: dyspnea, anorexia, weight loss greater than 15% or colitis. The animal will be euthanized at the specified time points or when clinical disease is considered non-reversible, #5 on scoring evaluation (See below).

SCORING:
0 = no signs
1 = ruffled fur,
2 = ruffled fur & weight loss <5%
3 = ruffled fur, hunched posture & weight loss > 5%
4 = ruffled fur, hunched posture & weight loss > 10%
5 = ruffled fur, hunched posture & weight loss > 15% OR paralysis of limb(s) OR colitis OR respiratory distress
6 = ruffled fur, hunched posture & weight loss ≥ 20% OR paralysis of limb(s) OR respiratory distress
7 = death
Euthanasia will occur at a score of 5

Column E Explanation Form For Regulated Species

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1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 17

3. Species (common name) of animals used in this study: Mesocricetus auratus (Syrian golden hamster)

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):

Nipah virus infection causes lethal disease in hamsters which closely mimics human disease (acute respiratory distress, encephalitis). In order to develop and characterize the immune response and vaccine efficacy we propose to use an established small rodent disease model, the Syrian hamster.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):

The utilization of an animal disease model is essential for studying pathogenesis as well as the efficacy testing of vaccine candidates and anti-virals. The potential illness experienced by some of the animals exposed to Nipah virus must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Search of the literature (Pubmed) indicates that NSAIDs cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis as was stabilization of lysosomal membranes that may reduce the release of cytokines. In addition, certain classes of NSAIDs have been documented to alter the replication of viruses. Opiates are not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we will use clinical evaluation that will allow us to determine the humane endpoint for euthanasia.

Column E Explanation Form For Regulated Species

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1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 63

3. Species (common name) of animals used in this study: Syrian hamster (Mesocricetus auratus)

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):
Andes virus causes lethal hantavirus pulmonary syndrome (HPS)-like disease in Syrian hamsters. Currently the Andes virus / hamster model of HPS is the only small animal model available for the study of hantavirus pathogenesis and potential therapeutics, therefore at this time it is the only model with which we can study the protective efficacy of effect of HPS vaccines.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):

In these experiments hamsters will be infected with a challenge dose of Andes virus which has previously been determined to cause lethal disease in 100% of animals. Following challenge, infected hamsters will appear normal until around 8 or 9 days post infection, after which they will demonstrate signs of disease including respiratory insufficiencies and death within approximately 24 hours. It is the goal of these studies to test second generation vaccine vectors for their protective efficacy following administration prior to or after ANDV challenge in the HPS hamster model in order to define the most potent candidate vaccine for prophylactic vaccination and post-exposure treatment. Animals receiving the experimental hantavirus vaccines may experience mild to moderate signs of illness and still recover, therefore, they will be euthanized if they appear to have entered the terminal stages of disease (i.e respiratory distress). Control animals will be euthanized when breathing insufficiencies first become apparent. The use of analgesics could alter the pathogenic and immunologic response to infection or post-exposure immunization, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production. Moreover, opioids can suppress NK cell activity. Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release and respiratory depression. Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages, inhibit interferon-alpha release from dendritic cells, and increase the synthesis and release of IL-10 from human macrophages. Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. In summary, alleviating the pain or discomfort with analgesics in immunized hamsters could directly interfere with the disease progression of the virus, thereby making the data collected impossible to interpret.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 11**

3. **Species (common name) of animals used in this study: Mesocricetus auratus (Syrian golden hamster)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):**

Nipah virus infection causes lethal disease in hamsters which closely mimics human disease (acute respiratory distress, encephalitis). In order to develop and characterize the immune response and vaccine efficacy we propose to use an established small rodent disease model, the Syrian hamster.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):**

The utilization of an animal disease model is essential for studying pathogenesis as well as the efficacy testing of vaccine candidates and anti-virals. The potential illness experienced by some of the animals exposed to Nipah virus must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Search of the literature (Pubmed) indicates that NSAIDs cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis as was stabilization of lysosomal membranes that may reduce the release of cytokines. In addition, certain classes of NSAIDs have been documented to alter the replication of viruses. Opiates are not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we will use clinical evaluation that will allow us to determine the humane endpoint for euthanasia.

Column E Explanation Form For Regulated Species

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1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 19

3. Species (common name) of animals used in this study: Cavia porcellus (Guinea pigs)

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):

Lujo virus infection in adult strain 13 Guinea pigs results in a systemic infection with internal hemorrhage and multi-organ failure leading to death. Currently there is no other disease model described for Lujo virus, therefore strain 13 Guinea pigs are the only in vivo option to evaluate medical countermeasures against this highly pathogenic arenavirus.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):

Experimental manipulations will be done while the animals are anaesthetized. However since we are assessing the therapeutic benefit of treating Lujo virus infection with ribavirin, we are unable to alleviate the disease progression in animals. Ribavirin has several hypothesized modes of action, one of which is modualating the host's immune repsonse. Upon injection with Lujo virus Guinea pigs are expected to develop signs disease which will include lethargy, weight loss and breathing distress, which ultimately leads to death. The illness experienced by the animals exposed to Lujo virus must not be treated because treatment will potentially interfere the pathogenesis of the disease and/or the effect of ribavirin treatments. Importantly, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production (1, 2). Moreover, opioids can suppress NK cell activity (3). Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release (4, 5) and respiratory depression (6). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages (7), inhibit interferon-alpha release from dendritic cells (8), and increase the synthesis and release of IL-10 from human macrophages (9). Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process, which is hypothesized to be important in HPS disease progression. Studies by Piersma et al. provide a final example of how analgesics may modify the expression of the disease (10). These investigators, using an established murine model of endotoxemia, showed that the opioids fentanyl and buprenorphine directly altered the outcome of their experiments by modulating the immune response. In this case, both of the opioids caused significant decreases in circulating levels of tumor necrosis factor-alpha following administration of LPS.

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4.Stellato C, Cirillo R, de Paulis A, et al. 1992. Human basophil/mast cell releasability. IX. Heterogeneity of the effects of opioids on mediator release. Anesthesiology. 77: 932-940.
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6.10. Piersma FE, Daemen MA, Bogaard AE, Buurman WA. 1999. Interference of pain control employing opioids in in vivo immunological experiments. Lab Animal 33: 328-333.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 4**

3. **Species (common name) of animals used in this study: Cynomolgus macaques (Macaca fascicularis)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):**

Macaques are the model of choice for Ebola viruses and the best surrogate model for human disease. Therefore, we would like to conduct this study in the nonhuman primate model. We propose to use Cynomolgus macaques since earlier studies with the 1989/90 strains have revealed that Cynomolgus macaques are most susceptible among tested nonhuman primate species. In this study we want to compare the pathogenic potential of both Reston ebolaviruses (REBOVs), the swine- derived REBOV strain, REBOV-08, and the REBOV-89/90 strain in NHPs. NHPs are generally valued as a the best surrogate model for human disease in Ebola virus research. Although so far there are no human cases known for REBOV, this virus is closely related to the other human-pathogenic species like Zaire ebolavirus (ZEBOV), which cause case fatality rates up to 90% in humans. ZEBOV has been shown to cause disease in pigs and can be transmitted from pigs to NHPs [11, 12]. For REBOV, as a closely related pathogen to ZEBOV, the potential to spread from infected pigs to humans remains (see World Health Organization Report, page #14). This study will advance work previously done in rodents and give more insight into REBOV pathogenicity in NHPs.

We have previously performed a comparative study in knockout mice with REBOV-89/90 and REBOV-08. This study determined a higher virulence for the macaque-derived isolate from 1989/90 indicating distinct pathogenic potentials for certain REBOV strains. Macaques are the gold standard animal disease model for Ebola viruses and the best surrogate model for human disease. Therefore, we would like to move into the nonhuman primate
model. We propose to use Cynomolgus macaques since earlier studies with the 1989/90 strains have revealed that Cynomolgus macaques are most susceptible among tested nonhuman primate species.
Reston ebolavirus (REBOV) causes significant disease, which is associated with distress in nonhuman primates. Causing infection in nonhuman primates is unavoidable in order to study virulence and disease progression. The investigator will notify the facility and RMVB staff when animals begin the Column E study. Staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are seen: dyspnea, anorexia, paralysis, unable to move from the ground of the cage, and significant weight loss (>15%). The animals will be euthanized at the specified time points or when clinical disease progression is considered irreversible (based on the clinical evaluation by the veterinarian in consultation with PI.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):**

Animals infected with Reston ebolavirus (REBOV) will experience pain and distress and the infection can be lethal. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, and stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target organ systems that are being evaluated in this study. Opiates are not indicated since they have depressant effects on the cardiovascular and respiratory systems and could alter the parameters to be measured and even accelerate the pathology and death. Instead we have established a scoring sheet that will allow us to determine the humane end point for euthanasia. The illness experienced by the animals exposed to REBOV must not be treated with analgesics because such treatment will interfere with studying the pathogenesis of the disease.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 8**

3. **Species (common name) of animals used in this study: cynomolgus macaque (macaca fascicularis)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (from ASP Section F):**

Currently the Cynomolgus macaque is the the best surrogate model for human influenza disease. Available data indicate that Cynomolgus macaques will develop different degrees of respiratory disease following influenza A virus infection by intrabronchial installation. Veterinary staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are seen: dyspnea, anorexia, paralysis, unable to move from the ground of the cage, and significant weight loss (>15%). The animals will be euthanized at the specified time points or when clinical disease progression is considered irreversible (based on the clinical evaluation by the veterinarian in consultation with PI.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):**

Animals inoculated with influenza A H7N 9 and HPAIV H7N7 viruses may experience pain and distress and the infection may even be lethal. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target systems that are being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise, which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. We have established a scoring sheet that will allow us to determine the humane end point for euthanasia for the non-human primates.

Column E Explanation Form For Regulated Species

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 3**

3. **Species (common name) of animals used in this study: rhesus macaque (Macaca mulatta)**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected (from** ASP Section F):

Infection of rhesus macaques with MERS-CoV results in fever, increased respiration rate, cough, piloerection and hunched posture, as such disease progression will be closely monitored using scoring systems established for previous respiratory disease models. Currently rhesus macaques are the only known animal model for MERS-CoV. Available data indicate that rhesus macaques can be infected with MERS-CoV and develop respiratory disease.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (from ASP, Section F):**

Animals inoculated with the novel coronavirus may experience pain and distress and the infection may even be lethal. NSAIDS cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target systems that are being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise, which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. We have established a scoring sheet that will allow us to determine the humane end point for euthanasia for the non-human primates.

Column E Explanation Form For Regulated Species

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1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 18

3. Species (common name) of animals used in this study: Syrian hamsters (*Mesocricetus auratus*)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** (*from ASP Section F*)

Andes virus causes lethal hantavirus pulmonary syndrome (HPS)-like disease in Syrian hamsters. Currently the Andes virus / hamster model of HPS is the only small animal model available for the study of HPS disease and potential therapeutics or vaccines, therefore at this time it is the only model with which we can study the protective efficacy of T-705 therapy. Animals receiving T-705 will be euthanized if they appear to have entered the terminal stages of disease (i.e. ruffled fur, hunched posture, weight loss ≥ 15%, and/or respiratory distress). Control (vehicle treated) animals will be euthanized when breathing insufficiencies become apparent.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. *(from ASP, Section F)*

In these experiments hamsters will be infected with a challenge dose of Andes virus which has previously been determined to cause lethal disease in 100% of animals. Following challenge, infected hamsters will appear normal until around 9 or 10 days post infection, after which they will demonstrate signs of disease including respiratory insufficiencies and death within approximately 24 hours. It is the goal of these studies to determine if the administration of T-705 can prevent or reduce mortality associated with lethal HPS disease in this animal model. As such, animals receiving T-705 will be euthanized if they appear to have entered the terminal stages of disease (i.e. ruffled fur, hunched posture, weight loss ≥ 15%, and/or respiratory distress). . Control (vehicle treated) animals will be euthanized when breathing insufficiencies become apparent.

The use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production. Moreover, opioids can suppress NK cell activity. Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release and respiratory depression. Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages, inhibit interferon-alpha release from dendritic cells, and increase the synthesis and release of IL-10 from human macrophages. Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. In summary, alleviating the pain or discomfort with analgesics in treated hamsters could directly interfere with the disease progression of the virus and/or the immune mediated protection, thereby making the data collected impossible to interpret.

EXPLANATION FOR COLUMN E LISTING FOR REGULATED SPECIES

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1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study: **2**

3. Species (common name) of animals used in this study: ***Grammomys surdaster* (African thicket rats)**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   Infection of the African thicket rat with the murine malaria parasite *P. berghei* (originally isolated from this species of rodent) is not supposed to be lethal; however, some of the infected animals showed some signs of sickness, such as ruffled fur, hunched posture, and/or reluctance to move (lethargy). In order for us to properly characterize this novel system, we needed to let the malarial parasite infection progress to a point of definitive sickness before we intervene with curative therapeutics.

   The state described above (ruffled fur, hunched posture, and/or lethargy) appeared in some of the thicket rats, and at anywhere from four days to up to two weeks following infection with the malaria parasite. Experience showed that most animals infected with the *P. yoelii* 17X (non-lethal) malaria parasite progressed to this state and then mounted a sufficiently effective immune response for spontaneous and complete recovery within a few (3 to 5) days.

   Two of our African thicket rats infected with malaria parasites did show signs of sickness, including ruffled fur and hunched posture.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   Analgesics would not have relieved the modest distress due to the infection. Once we saw far the clinical signs progressed (nothing more than piloerection, hunched posture, and lethargy – this parasite (*P. berghei*) di**dn't cause significant** parasitemia and anemia in the thicket rat host), we cured the affected animals with anti-malarial drugs or euthanized them for sample collection.

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   Animals were given extra food treats on cage floor and extra bedding for nesting.

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1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study: **14**

3. Species (common name) of animals used in this study: ***Graphiurus kelleni* (Kellen's African dormouse)**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   Dormice were infected intranasally with a vaccinia virus expressing firefly luciferase and imaged daily. Two different volumes of inocula were used in order to determine the route and extent of virus spread. Dormice are exquisitely sensitive to poxvirus infection and are one of only a few models available for studying monkeypox virus pathogenesis.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   Analgesics were not used because they would cause profound effects on the immune system and thus would impair proper evaluation of immune responses. Full evaluation of disease progression would be compromised by use of pain relief. Animals were observed and weighed daily; if they exhibited clinical signs of extreme lethargy or weight loss, they were humanely euthanized.

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   Animals infected with vaccinia virus were provided moistened feed or other food supplementation on the cage floor.

EXPLANATION FOR COLUMN E LISTING FOR REGULATED SPECIES

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1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study: **50**

3. Species (common name) of animals used in this study: ***Mustela putorius furo* (common ferret)**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   This project is to develop vaccines to protect humans against respiratory viruses, namely highly pathogenic avian influenza viruses. Viral infection and the induction of an immune response can only be studied in living animals. We are limited in our ability to study these virus infections and vaccine responses in the natural human host or in permissive primate models because of limited availability, limited genetic tools, and ethical considerations. Ferrets are good mammalian models to study influenza disease and to evaluate potential vaccine candidates. Avian influenza viruses are not uniformly virulent for ferrets. Infection of ferrets with some highly pathogenic avian influenza viruses can result in clinical signs of disease that can range from very mild disease up to pneumonia and even, if unintervened, death. In this regard, it resembles the rare avian influenza infections reported in humans.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   For the attenuation studies, we conducted studies to evaluate the level of attenuation of live vaccine candidate viruses compared to the wild-type viruses that cause the disease in nature. H5N1 wild-type influenza viruses have been shown to cause severe clinical signs in ferrets (Zitzow *et al.* 2002). Since the attenuation studies measure the ability of the virus to replicate in the animal, and some influenza virus subtypes cause clinical signs in ferrets, we did not administer antivirals or antipyretics/analgesics to animals that showed clinical signs. There are two reasons why nonsteroidal anti-inflammatory drugs (NSAIDs) were not administered to attenuation-study ferrets that exhibit fever. One reason is that understanding the fever response to these infectious agents is an important endpoint of validating this model and these viruses. Secondly, anti-inflammatory properties of the NSAID will affect the immune response to the viruses, which may affect the course of the disease. However, the clinical signs observed were not severe in the time period of the studies (up to 5 days post-infection).

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   For generation of antisera, viral replication is necessary to generate the antibody response in the ferrets, so antivirals were not administered to ferrets inoculated with wild-type viruses. Antisera-generation ferrets that showed signs of significant illness, for example, high fever (>105°F for more than 24 hours), pronounced lethargy, respiratory distress, or dehydration, were given fluids and supportive care including approved antipyretics and/or analgesics at the discretion of the facility veterinarian.

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EXPLANATION FOR COLUMN E LISTING FOR REGULATED SPECIES

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1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study: **6**

3. Species (common name) of animals used in this study: ***Macaca mulatta* (Rhesus macaque)**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   Severe malaria disease resulting from *P. coatneyi* infection is a possibility in our study. Rhesus macaques were chosen because they present with similar clinical signs and disease pathology when infected with *P. coatneyi* as seen in *P. falciparum*-infected humans.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   Systemic analgesics and pain-relieving measures were not used because they would have interfered with the experimental results by altering immune and/or inflammatory responses as well as the animal's compensatory physiological responses. Treatment of *P. coatneyi* infection with anti-malarials would have interfered with the diagnosis of clinical endpoints used in this study. These clinical criteria are necessary for the diagnosis of severe malaria and for comparisons with the clinical signs of disease seen in *P falciparum*-infected humans.

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   Palliative measures were taken to keep the animals comfortable. A variety of fruits and treats were offered to animals that were not eating normally. For animals that became severely anorexic, i.e., not eating for 24 or more hours, orogastric tube feeding a nutritional supplement or biscuit slurry was performed. Those animals were offered highly palatable food items such as Ensure, Pediasure, primatreats, Gatorade, banana mash, pudding, peanut butter sandwiches, and other diet modifications.
   Animals that became dehydrated from not drinking or excessive fluid loss through diarrhea were administered fluids IV, IP or SC.

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1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study: **2**

3. Species (common name) of animals used in this study: ***Macaca mulatta* (Rhesus macaque)**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   Animals that developed immunodeficiency as a result of SHIV or SIV infection frequently experienced **anorexia, weight loss and/or** diarrhea. In previous experiments, most animals were euthanized before clinical signs became evident, and evidence of disease **only** became apparent post-mortem. For example, Pneumocystis-induced disease, giant cell pneumonia, and meningoencephalitis have been demonstrated histopathologically at the time of necropsy, but were not clinically evident prior to euthanasia. Vital signs in these animals have remained within normal limits.

   Some SHIV- or SIV-infected animals also exhibited neurological signs or signs of respiratory distress. From previous experiments using a specific neurotropic viral strain, the animals developed tremor, balance issues, head tilt, difficulty perching and ataxia/poor motor coordination.

   Diagnostics were performed at the discretion of the attending veterinarian. The diagnostics included but were not limited to: rectal culture with sensitivity, radiographs, and CBC/Differential with Serum Chemistry.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   Animals inoculated with neurovirulent SIV were allowed to progress to clinical signs of SIV disease, including neurological signs such as tremor, head tilt, and ataxia, in order to allow us to distinguish by the PET and MRI scans (and post-euthanasia pathology) any alterations in the dopaminergic and/or serotonergic systems similar to those observed in AIDS patients. Anti-retroviral therapies were not used, because they would subvert the purpose of the experiments. NSAIDS such as ibuprofen and ketoprofen cannot be used because they would interfere with the immune response of the animals on study, which might be highly pertinent to the development of neuropathy. Study animals with signs of discomfort received non-NSAID analgesics (i.e., buprenorphine) at the discretion of the attending veterinarian.

   Palliative measures were taken to keep the animals comfortable. A variety of fruits and treats were offered to animals that were not eating normally. For animals that became severely anorexic, i.e., not eating for 24 or more hours, orogastric tube feeding a nutritional supplement or biscuit slurry was performed. Those animals were offered highly palatable food items such as Ensure, Pediasure, primatreats, Gatorade, banana mash, pudding, peanut butter sandwiches, and other diet modifications.

   Animals that became dehydrated from not drinking or excessive fluid loss through diarrhea, were administered fluids IV, IP or SC.

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   Supportive care was administered at the discretion of the attending veterinarian. The care included, but was not limited to fluid therapy, the use of antibiotics and anti-diarrhea medications, orogastric tube feeding under sedation, offering highly palatable food items such as Ensure, Pediasure, primatreats, Gatorade, banana mash, pudding, peanut butter sandwiches, and other diet modifications.

EXPLANATION FOR COLUMN E LISTING FOR REGULATED SPECIES

This form is intended as an aid to completing the USDA Annual Report of Research Facilities Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study:
   3 African green monkeys
   6 macaques
   3 Squirrel monkeys.

3. Species (common name) of animals used in this study:
   ***Chlorocebus aethiops* (African green monkey)**
   ***Macaca mulatta* (Rhesus macaque)**
   ***Saimiri sciureus* (Squirrel monkey).**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   Influenza A virus infection can cause pneumonia associated with distress in non-human primates. Also, co-infection with *Streptococcus pneumoniae* causes distress in humans. Recreating disease, and possibly serious disease, in non-human primates is necessary in order to develop and evaluate animal models to study pathogenesis and vaccine development.
   The investigator notified the facility staff when animals began the Column E study. The veterinary staff monitored the animals, and the investigator was notified when the animals became clinically ill. The animals were euthanized at the specified time points or when clinical end-point was reached, based on the clinical evaluation by the veterinarian.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   Animals infected with the 2009 pandemic human influenza A virus (H1N1) will likely experience pain and distress, but the viral infection is typically non-lethal. However, infection with the 1918 H1N1 virus or co-infection with *Streptococcus pneumoniae* may increase severity of influenza infection and may be lethal.
   NSAIDS were not used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis, stabilization of lysosomal membranes that may reduce the release of cytokines. These affected systems are target systems that were being evaluated in this study.
   Opiates were not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we established a scoring sheet that helped us to determine the humane endpoint for euthanasia.

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   Palliative measures were taken to keep the animals comfortable. A variety of fruits and treats were offered to animals that were not eating normally. For animals that became severely anorexic, not eating for 24 or more hours, orogastric tube feeding a nutritional supplement or biscuit slurry was performed. Those animals were offered highly palatable food items such as Ensure, Pediasure, primatreats, Gatorade, banana mash, pudding, peanut butter sandwiches, and other diet modifications.
   Animals that became dehydrated from not drinking or excessive fluid loss through diarrhea, were administered fluids IV, IP or SC.

COLUMN E Explanation Form

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1 **Registration Number:** 51-F-0016

2 **Number of animals used under Column E conditions in this study: 6**

3 **Species (common name) of animals used in this study**: Common marmoset

4 **Explain the procedure producing pain and/or distress, including reason (s) for species selected:**
The marmosets in this protocol will be used for the animal model for multiple sclerosis (MS), experimental autoimmune encephalomyelitis (EAE) and another animal model of demyelination, Cuprizone. EAE is induced by subcutaneous injections of human white matter homogenate in an adjuvant containing Mycobacteria tuberculosis, to incite an immune response. A major hallmark of MS is demyelination, a process in which neurons lose the myelin sheath insulating the axon. Understanding how demyelination can be measured with MR imaging is a major goal of this work. Cuprizone, a well-known copper-chelating agent, has been shown to induce highly-reproducible, reversible demyelination in mice (and to a lesser extent in rats) following oral ingestion. Cuprizone-induced demyelination is characterized by degeneration of the myelin-producing cells in the brain. These diseases may result in the development of various neurological deficits, including ataxia and paralysis, which while not being painful to the animals, it will impair their ability to move around their environment. This species was selected because marmosets are well-established systems of EAE. It is increasingly apparent that marmoset EAE (relative to rodent EAE) has superior translational applicability, which is ideal for a drug study. This is due to the fact that marmoset EAE shares highly relevant similarities with MS such as CD8 T-cell involvement, the presence of brain and spinal cord lesions and importantly, the ability for MRI analysis of lesions. Moreover, marmosets are particularly appropriate for studies involving MRI monitoring because their white matter/grey matter ratio resembles that of humans, which is relevant to both the EAE and Cuprizone studies.

5 **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**
As EAE is a relapsing, remiting disease, we expect the extent and duration of neurological symptoms to differ for each animal and anticipate that some marmosets may recover. While we do not expect the marmosets to be in pain, restriction of movement may cause distress to the animals. Marmosets will be allowed to progress clinically to the point of hind limb paralysis and to remain in this state for up to 48 hours; to allow for recovery before euthanasia. To mitigate distress to the animals during this time, we plan to provide access to food and water on multiple levels of the cages, provide heating discs and express bladders as needed. Marmosets unable to ambulate around the cage will be housed individually in a padded kennel with easy access to food and water.

Column E Explanation Form for Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study.** 24

3. **Species (common name) of animals used in this study.** Nonhuman Primates

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.**

   To date, infection of nonhuman primates with orthopoxviruses has produced disease which most closely resembles the sequelae of human infection. The requirements for proof of protection in NHPs by vaccines and therapeutics intended for use in humans demand that the pathogenesis of the disease and correlates of immunity be understood in NHPs. Many immunological assays developed for humans can be performed on NHPs due to the phylogenic relatedness of these two species. These considerations make macaques the most appropriate animal models to study human poxvirus infections.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

   The infection will likely result in serious disease that must not be treated with analgesics because treatment will interfere with the pathogenesis of the disease, and thus prevent our ability to examine normal viral infection and host response to the infection. Analgesics, both non-steroidal anti-inflammatory drugs (NSAIDS) like aspirin and ibuprofen, and acetaminophen, and opioids (narcotics) can have a profound effect on the immune system which would alter the pathogenic and immunologic response to infection, thus making it not feasible to interpret the data obtained in the study. We need to measure the number of immunological parameters in the study to elucidate and further characterize the mechanisms of poxvirus pathogenesis and to attempt to identify correlates of protection.

EXPLANATION FOR COLUMN E LISTING FOR REGULATED SPECIES

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1. Registration Number: **51-F-0016**

2. Number of animals used under Column E conditions in this study: **214**

3. Species (common name) of animals used in this study: ***Mesocricetus auratus* (Syrian Hamster)**

4. Explain the procedure producing pain and/or distress, including reason (s) for species selected.

   Leishmanial diseases are major parasitic diseases of man. The stage of the parasite that grows in the vertebrate host and causes disease cannot be generated *in vitro*. It can only be obtained from *in vivo* sources. In nature, most leishmanial species are maintained within animal reservoirs, usually rodents. The hamster is the only laboratory animal that develops visceral leishmaniasis. There is no way to test the action of vaccines *in vitro*. The whole animal is required to study experimental vaccines, protective immune responses and the outcome of infection of vaccinated animals. Information derived from the immune system responses being examined cannot be gathered by using cell culture or computer models.

   Visceral leishmaniasis in hamsters is manifested as hepatomegaly and anemia. The progression of visceral infection in hamsters is not associated with any overt pathology or changes in behavior until infection is severe, at which time hamsters begin to move slowly and lose their appetite.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine (personal experience or literature search) that pain and/or distress relief would interfere with test results.

   The point of onset of morbidity was variable, but generally occured in the period 12 to 16 weeks post infection (when parasite inoculum was low and parasites were injected intradermally). Without intervention, over several weeks, the affected hamsters would have become cachectic, moribund, and eventually die.

   The only means for pain or distress relief was euthanasia. Analgesia was not be used during the two-day period after morbidity was observed, because this intervention would have affected the infected organs that were evaluated for size, histology, and parasite load as an endpoint to compare vaccinated and non-vaccinated animals.

6. Indicate the supportive care and humane measures provided to the animals on these studies.

   Infected hamsters were euthanized before any major signs of distress developed due to visceral leishmaniasis.

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study: 6**

3. **Species (common name) of animals used in this study:** Syrian Golden Hamster (*Mesocricetus auratus)*

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** *(from ASP, Section F)*

Following infection with orthobunyaviruses, some hamster may demonstrate signs of disease which could include weight loss, encephalitis or other neurological and/or hemorrhagic signs. Infection with some of these viruses may also result in a lethal outcome. To the best of our knowledge, hamsters have not been rigorously assessed as potential animal model for the viruses being studied; although limited evidence suggests that they may serve as a lethal disease model for Bunyamwera virus. Further, they have been shown to be highly susceptible to several other Bunyaviruses, as well as being excellent models for other hemorrhagic fever diseases. Animal health will be evaluated twice daily during the acute phase of disease (see experimental end point for scoring criteria) and will be euthanized when they reach a point of advanced disease according to scoring criteria.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

It is the goal of this study to evaluate the ability of hamsters to serve as an infection/disease model reflecting human virulence among orthobunyaviruses. To this end, in these experiments hamsters will be infected with potentially lethal challenge doses of Bunyamwera virus, Batai virus and Ngari virus. While we cannot rule out the possibility that some animals will develop signs of terminal disease, infected animals will be euthanized if they enter an advanced stage of disease as determined by scoring criteria. The signs of disease cannot be relived as treatment may interfere with immunopathological events associated with disease progression, as judged by an extensive review of the scientific literature. In particular, the use of analgesics could alter the pathogenic and immunologic response to infection, thus making it impossible to interpret the data obtained in this study. Narcotic analgesics have been shown to interfere with mechanism(s) responsible for interferon production, which are known to be important in resistance to bunyavirus infection. Similarly, opioids can suppress NK cell activity. Of particular importance in this study is the fact that analgesics including buprenorphine can cause histamine release and respiratory depression. Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. Histamine has been shown to induce activation of human macrophages, inhibit interferon-alpha release from dendritic cells, and increase the synthesis and release of IL-10 from human macrophages. Clearly, the analgesic-induced release of histamine would directly interfere with the inflammatory process. In summary, alleviating the pain or discomfort with analgesics could directly interfere with the disease progression of the virus and/or the immune mediated protection, thereby making the data collected impossible to interpret.

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 28

3. Species (common name) of animals used in this study: *Mesocricetus auratus* (Syrian golden hamster)

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** *(from ASP Section F)*

Nipah virus challenge causes lethal disease in hamsters which closely mimics human disease (acute respiratory distress, encephalitis). In order to develop and characterize the immune response and vaccine efficacy we propose to use an established small rodent disease model, the Syrian hamster.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** *(from ASP, Section F)*

The utilization of an animal disease model is essential for studying pathogenesis as well as the efficacy testing of vaccine candidates and anti-virals. The potential illness experienced by some of the animals exposed to Nipah virus must not be treated with analgesics because treatment will interfere with the disease manifestation thus rendering the data collected unreliable. Search of the literature (Pubmed) indicates that NSAIDs cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis as was stabilization of lysosomal membranes that may reduce the release of cytokines. In addition, certain classes of NSAIDs have been documented to alter the replication of viruses. Opiates are not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we will use clinical evaluation that will allow us to determine the humane endpoint for euthanasia. Therefore, animals will be assessed/scored when presenting with signs of disease according to the following criteria: 0 = no signs of disease; 1 = ruffled fur; 2 = ruffled fur & weight loss <5%; 3 = ruffled fur, hunched posture & weight loss > 5%; 4 = ruffled fur, hunched posture & weight loss > 10%; 5 = ruffled fur, hunched posture, weight loss > 15%, or encephalitic signs, or hemorrhagic signs, or paralytic signs or dyspnea; 6 = ruffled fur, hunched posture, weight loss > 20%, or encephalitic signs, or hemorrhagic signs, or paralytic signs, or dyspnea; 7 = death. Euthanasia will occur at a score of 5.

Column E Explanation Form For Regulated Species

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1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study: 22

3. Species (common name) of animals used in this study: *Mesocricetus auratus* (Syrian hamster)

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected. *(from ASP Section F)*

Infection of hamsters with MA-ZEBOV, hamsters are susceptible to mouse adapted Ebola, could cause distress in immunocompetent animals. Recreating disease, and possibly serious disease, in these animals is necessary in order to test the efficacy of the treatments proposed. The investigator will notify the facility staff when animals begin the Column E study. The veterinary and/or program staff will monitor the animals and the investigator will be notified when the animals are clinically ill or the following signs of morbidity are observed: dyspnea, anorexia, weight loss greater than 15%. The animal will be euthanized at the specified time points or when clinical disease is considered non-reversible. Hamsters are used other small animals do not appear to recapitulate all aspects of disease caused by Ebola virus to the extent that hamsters do.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. *(from ASP, Section F)*

Hamsters infected with MA-ZEBOV may experience pain and distress and the infection may be lethal. Search of the literature (Pubmed) indicates that NSAIDs cannot be used because these drugs produce profound effects on the immune system, such as inhibition of prostaglandin and leukotriene synthesis as was stabilization of lysosomal membranes that may reduce the release of cytokines. In addition, certain classes of NSAIDs have been documented to reduce VSV replication – which could be extrapolated to affect ZEBOV replication. These affected systems are target systems being evaluated in this study. Opiates are not indicated since the pain produced consists of a non-specific malaise which would likely not be affected by opioids. Many opioids could also increase mortality due to effects on the cardiovascular or respiratory systems. Instead we will use daily clinical evaluation that will allow us to determine the humane endpoint for euthanasia.

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **32** of animals used in this study.

3. Species (common name) **swine** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Thirty-two (32) minipigs were exposed percutaneously. The test agents used are military grade chemical agents. The compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   During exposure, toxic signs were observed to provide for the accurate assessment and toxic properties of the test material. Therefore, no anesthesia, analgesics, or tranquilizers were used during the actual exposures. Their use would have interfered with the evaluation of toxic signs and the ability to observe onset of signs.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **17** of animals used in this study.

3. Species (common name) **guinea pigs** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Seventeen (17) guinea pigs were exposed, via nose-only inhalation, to lethal and sub-lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   During exposure, toxic signs were observed to provide for the accurate assessment and toxic properties of the test material. Therefore, no anesthesia, analgesics, or tranquilizers were used during the actual exposures. Their use would have interfered with the evaluation of toxic signs and the ability to observe onset of signs.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **48** of animals used in this study.

3. Species (common name) **guinea pigs** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Forty-eight (48) guinea pigs were exposed, via whole-body inhalation, to lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   During exposure, toxic signs were observed to provide for the accurate assessment and toxic properties of the test material. Therefore, no anesthesia, analgesics, or tranquilizers were used during the actual exposures. Their use would have interfered with the evaluation of toxic signs and the ability to observe onset of signs.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **234** of animals used in this study.

3. Species (common name) **guinea pigs** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   One Hundred Twenty-seven (127) guinea pigs were exposed, via nose-only inhalation, to lethal concentrations. One Hundred Seven (107) guinea pigs were exposed, via nose-only inhalation, to no-observable adverse effects levels (NOAEL) concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   During exposure, toxic signs were observed to provide for the accurate assessment and toxic properties of the test material. Therefore, no anesthesia, analgesics, or tranquilizers were used during the actual exposures. Their use would have interfered with the evaluation of toxic signs and the ability to observe onset of signs. Also, their use could potentially have affected the lethal results through pre-exposure enhancement of liver metabolism. This potential metabolic enhancement could have shifted the lethality or NOAEL results and render the study potentially invalid.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **44** of animals used in this study.

3. Species (common name) **rabbits** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Forty-four (44) rabbits were exposed, via whole-body inhalation, to lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   During exposure, toxic signs were observed to provide for the accurate assessment and toxic properties of the test material. Therefore, no anesthesia, analgesics, or tranquilizers were used during the actual exposures. Their use would have interfered with the evaluation of toxic signs and the ability to observe onset of signs. Also, their use could potentially have affected the lethal results through pre-exposure enhancement of liver metabolism.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **58** of animals used in this study.

3. Species (common name) **rabbits** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Fifty-eight (58) rabbits were exposed dermally to lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   This was an LD_{50} (dose that is lethal to 50% of the animals tested) study. In LD_{50} studies, it is essential to allow the animals to progress to death or recovery. Attempting to alleviate pain that was associated with the observed toxic signs could have interfered with the study's technical endpoint.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **16** of animals used in this study.

3. Species (common name) **rabbits** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Sixteen (16) rabbits were exposed dermally to lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   In this study, it was necessary to allow the animals to progress to death or recovery, per federal guidelines. Attempting to alleviate pain that was associated with the observed toxic signs could have interfered with the study's technical endpoint.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency **Department of Transportation** CFR **49, Part 173.133 (3/29/12 Edition)**
   Agency **Department of Transportation** CFR **49, Part 173.132, Class 6, Division 6.1**

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **116** of animals used in this study.

3. Species (common name) **rabbits** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   One-Hundred Sixteen (116) rabbits were exposed dermally to lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   In this study, it was necessary to allow the animals to progress to death or recovery. Attempting to alleviate pain that was associated with the observed toxic signs could have interfered with the study's technical endpoint.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Column E Explanation

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1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number **2** of animals used in this study.

3. Species (common name) **rabbits** of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Two (2) rabbits were exposed, via nose-only inhalation, to lethal and sub-lethal concentrations. The test agents used are military grade chemical agents. These compounds caused toxic signs such as respiratory distress and seizures.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   During exposure, toxic signs were observed to provide for the accurate assessment and toxic properties of the test material. Therefore, no anesthesia, analgesics, or tranquilizers were used during the actual exposures. Their use would have interfered with the evaluation of toxic signs and the ability to observe onset of signs.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency _____ CFR _____

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 682 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Guinea pigs used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**

Agency N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 356 **of animals used in this study.**

3. **Species (common name)** Hamsters **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Hamsters used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**

Agency N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 260 **of animals used in this study.**

3. **Species (common name)** Non-human Primates **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Nonhuman primates used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)**

Agency N/A **CFR** N/A

NOV 2 9 2013

Column E Explanation

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1. Registration Number: 51-F-0024

2. Number 56 of animals used in this study.

3. Species (common name) Guinea Pig of animals used in the study.

4. Explain the procedure producing pain and/or distress.

ASP #1989-093

This protocol addresses the need for CBER to test the US Standard Diphtheria Antitoxin that is supplied to manufacturers to evaluate antitoxin products submitted for licensure, release, or IND testing as required by the Minimum Standards for Diphtheria. The Standard Antitoxin is also used by CBER to confirm manufacturers' test results showing that products are sufficiently potent to elicit neutralizing antibodies to Diphtheria Toxin. Animals are injects with a combination of toxin and antitoxin, then observed for 120 hours for protection against signs of Diphtheria.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Early signs of unprotected animals are lethargy and displays of rapid breathing. They are observed closely in the 120 hours post inoculations and can be euthanized given these signs are seen. However, death can be rapid and may occur between observation periods. There is no in vitro alternative for this assay.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA Minimum Standards CFR

NOV 2 7 2013

Column E Explanation

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1. Registration Number: 51-R-0031

2. Number 4 of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

4. Explain the procedure producing pain and/or distress.
   4 Rabbits received intra-articular injections

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below) Rabbits received an intra-articular injection to see the effects of the compounds used. Anti-inflammatory agents could not be used

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency_____ CFR_____

NOV 2 7 2013

Column E Explanation

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1. Registration Number: 51-R-0031

2. Number 32 of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   See attachment

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

   See attachment

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency_____ CFR_____

Attachment for USDA Report 2013- Washington Biotechnology

4.) The development of Arthritis.

5.) Anti-inflammatory agents cannot be used because the study was designed to determine the anti-inflammatory effects of proprietary compounds. Rabbits were used because proprietary compounds were known to be inactive in mice and rats.

Column E Explanation

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1. Registration Number: 51-R-0018

2. Number 1037 of animals used in this study.

3. Species (common name) Guinea pigs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Exposure to organophosphorous (OP) compounds to induce signs of OP toxicity potentially including neurotoxic and/or neurobehavioral effects, convulsions, or respiratory compromise

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

   The purpose of these studies is to develop countermeasures (antidotal therapies) against the acute and delayed effects of OP toxicity. The administration of OP compounds is unavoidable, as is the distress caused by the compounds - the testing of OP antidotes requires the presence of signs of toxicity to evaluate the effectiveness of the antidote in treating/reversing these signs. Animals are closely and continuously monitored during the OP exposure until no further signs of acute toxicity are present. Any animal showing signs of seizure activity accompanied by respiratory compromise or distress are immediately euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency NA CFR NA

Column E Explanation

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1. Registration Number: 51-R-0018

2. Number 23 of animals used in this study.

3. Species (common name) Rhesus macaques of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Radiation-induced injury. Animals receive whole-body irradiation at doses sufficient to cause temporary reversible supression of blood cell production.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

   Blood cell supression induced by radiation remains a significant concern for those exposed in radiation accidents or potential terrorist events. There are no FDA-approved drugs or biologics for treating the acute blood cell supression caused by these events. This model is used to test the treatment efficacy of drugs or biologics on the bone marrow (where blood cells are produced). NHPs receive aggressive supportive care/medical management including the use of pain medication from days 5-35 of the study (when blood cell levels are at their lowest), then as needed based on specific signs. Based on clinical findings and necropsy results the IACUC determined that the potential for unrelieved pain or distress warranted a category E classification even with the routine use of analgesic medications.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency FDA CFR Title 21 Parts 314&601

Column E Explanation

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1. Registration Number: 51-R-0018

2. Number 56 of animals used in this study.

3. Species (common name) Rhesus macaques of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   Radiation-induced injury (GI acute radiation syndrome; ARS). Animals receive whole-body irradiation at doses sufficient to cause GI toxicity.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

   GI toxicity induced by radiation remains a significant concern for those exposed in radiation accidents, potential terrorist events, an oncologic therapy treatments. There are no FDA-approved drugs or biologics for treating the ARS caused by these events. This model is used to test the treatment efficacy of drugs or biologics on the GI system. NHPs receive aggressive supportive care/medical management including the use of pain medication for the duration of study. Based on clinical findings and necropsy results the IACUC determined that the potential for unrelieved pain or distress warranted a category E classification even with the routine use of analgesic medications.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency FDA CFR Title 21 Parts 314&601

NOV 2 5 2013

Column E Explanation Form

1. **Registration Number:** 51-F-0031

2. **Number of animals used in this study:** 17

3. **Species (common name) of animals used in this study:** Guinea Pigs

4. **Explain the procedure producing pain and/or distress:**

[redacted]

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below):**

[redacted]

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):**

Agency: N/A **CFR: N/A**

NOV 27 2013

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Elizabeth Goldentyre
USDA
APHIS
Animal Care
920 Main Campus Drive, Suite 200
Raleigh, NC 27606-5213

Tuesday, November 26, 2013

Dr. Goldentyre,

During the past year Spring Valley Laboratories has had two animals in the USDA category of E. The first animal was a pregnant Guinea Pig who died over night giving birth. As a corrective action SVL technicians were trained more extensively to observe animals who are expected to give birth. The second animal was also a guinea pig. This animal had been bleed via the *vena cava* under anesthesia and recovered from anesthesia. However, over night the animal died. Upon necropsy by a veterinary pathologist it was determined that the animal likely died due to complications from the blood collection. Additional training of staff was conducted in order to notice signs of pain and distress.

Kind regards,

Spring Valley Laboratories, Inc.
PO Box 242
Woodbine, MD 21797
Phone: (b) (6), (b) (7)(C)
Fax: 410-795-2242
Email: (b) (6), (b) (7)(C)

Column E Explanation

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1. Registration Number: **51-R-0082**

2. Number of animals used in this study. **65**
   Study
   Scrapie Brain Pool Production For Use in Viral Clearance Dept for Spiking Test Material used for future Scrapie In Vivo Assays

3. Species (common name): **Hamster**

4. Explain the procedure producing pain and/or distress.

   The pain experienced is due to the development of scrapie clinical signs in hamsters. The In Vivo assay is currently the most sensitive assay for scrapie and the only method accepted by regulatory agencies for scrapie. Regulatory agencies are requiring that manufacturers show the efficacy of their manufacturing process in the removal of possible contaminants. Animals must be held until the terminal stage of the disease is observed, which include generalized tremor, abnormality of gait, ataxia and head bobbing. All clinical signs must be confirmed histopathologically (vacuolization of the brain).

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (for Federally mandated testing, see below)

   See 6. below.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g, APHIS, 9 CFR 113, 102).

   a. **"Federal Bulletin No. 40, 26 February 1994, German Federal Ministry of Health Guidelines on Safety Measures for Minimizing the Risk of transmission of BSE and Scrapie".**
   b. **"WHO Consultation of Medical and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies" (Geneva 24-26, March, 1997) and OIE Animal Health Code (May 1997) Concerning BSE.**
   c. **Committee for Proprietary Medicinal Products (CPMP) "Notes for Guidance Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products", (1997).**

Column E Explanation

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1. Registration Number: **51-R-0082**

2. Number of animals used in this study. **138 per study based on study design; 64 developed clinical signs of Scrapie**
   Study: AD44RH.195346.BSV

3. Species (common name): **Hamster**

4. Explain the procedure producing pain and/or distress.

   The pain experienced is due to the development of scrapie clinical signs in hamsters. The In Vivo assay is currently the most sensitive assay for scrapie and the only method accepted by regulatory agencies for scrapie. Regulatory agencies are requiring that manufacturers show the efficacy of their manufacturing process in the removal of possible contaminants. Animals must be held until the terminal stage of the disease is observed, which include generalized tremor, abnormality of gait, ataxia and head bobbing. All clinical signs must be confirmed histopathologically (vacuolization of the brain).

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (for Federally mandated testing, see below)

   See 6. below.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g, APHIS, 9 CFR 113, 102).

   a. **"Federal Bulletin No. 40, 26 February 1994, German Federal Ministry of Health Guidelines on Safety Measures for Minimizing the Risk of transmission of BSE and Scrapie".**
   b. **"WHO Consultation of Medical and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies" (Geneva 24-26, March, 1997) and OIE Animal Health Code (May 1997) Concerning BSE.**
   c. **Committee for Proprietary Medicinal Products (CPMP) "Notes for Guidance Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products", (1997).**

Column E Explanation

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1. Registration number. 51-R-0095.

2. Number 80 of Animals used in this study.

3. Species(Common name) Ferret of Animals used in the study

4. Explain the procedure producing pain and/or distress.

   To study the pathogenicity of influenza virus, Ferret were infected with influenza virus as the result of the infection clinical signs were observed

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with the result. (For federally mandated testing, see item 6 below)

   Scoring clinical signs after influenza virus infection is important in determining the pathogenicity of the virus as a result pain and /or distress relief would interfere with the scoring of the clinical signs.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number(e.g. APHIS, 9 CFR 113.102):

   Agency _____ CFR _____.